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内容

（[1]）EEA 相关性文本。

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以浅色字体打印标题的法案均为涉及农业日常管理的法案，一般在有限期内有效。

所有其他法案的标题均以粗体打印，并以星号开头。

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（立法法案）

法规

欧洲议会和理事会于 **2017** 年 **4** 月 **5** 日签发的关于医疗器械第 **2017/745** 号法规，修订了第 **2001/83/EC** 号指令，第 **178/2002** 号（**EU**）法规和第 **1223/2009** 号（**EU**）法规，并废除了理事会第 **90/385/EEC** 号和第 **93/42/EEC** 号指令

（EEA 相关性文本）

欧洲议会和欧盟委员会，

考虑到“欧盟运作条约”，特别是其中第 114 条和第 168（4）（c）条规定，

并考虑到欧盟委员会提案，

于立法草案转交各国议会后，

考虑到欧洲经济和社会委员会之意见（[1]），

在咨询地区委员之后，

根据一般立法程序运作（[2]），

鉴于：

(1) 理事会第 90/385/EEC 号指令（[3]）和理事会第 93/42/EEC 号指令（[4]）构成有关医疗器械（不包括体外诊断医疗器械）的欧盟监管框架。但需要对该指令进行大幅修订，以便建立稳健、透明、可预测和可持续的医疗器械监管框架，以确保高水平的安全和健康，同时为创新提供支持。

Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than in vitro diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) 本法规旨在确保区域内医疗器械市场的平稳运作，在为患者和使用者提供高水平健康保护的基础上，同时考虑到活跃于本行业的中小型企业利益。同时，本法规为医疗器械的质量及安全性制定了较高标准，以满足器械产品常见安全问题的管控。这两个目标相辅相成、不可分割地联系在一起，并且在达成过程中没有主次顺序。关于欧盟运作条约（TFEU）第 114 条，本法规融合了上市销售以及将医疗器械及其附件投入欧盟市场的规则，这些规则可能受益于货物自由流通原则。针对 TFEU 第 168(4)(c) 条，本法规通过确保临床研究的数据的可靠性和稳健性，来保障这些器械的质量及安全，并保障参与临床研究受试者的安全。

This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and

safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

（[1]） 2013 年 2 月 14 日意见（ OJ C 133, 9.5.2013, p. 52）。

（[2]） 2014 年 4 月 2 日的欧洲议会立场（尚未在官方公告内公布）以及 2017 年 3 月 7 日首次审阅时理事会的立场（尚未在官方公告内公布）。

（[3]） 1990 年 6 月 20 日签发的关于成员国有关可植入医疗器械法律的理事会第 90/38/EEC 号指令（ OJ L 331, 7.12.1998, p.1）。

（[4]） 1993 年 6 月 14 日签发的关于医疗器械的理事会第 93/42 EEC 号指令（ OJ L 169， 12.7.1993， p. 1）。

（3） 本法规并不寻求协调有关医疗器械投入使用后，在市场上进一步供应之规则，例如二手销售。

This Regulation does not seek to harmonise rules relating to the further making available on the market of medical devices after they have already been put into service such as in the context of second-hand sales.

（4） 应大大加强现有监管方法的关键要素，例如公告机构监管、符合性评估流程、临床研究和临床评价，警戒和市场监管，同时引入确保医疗器械透明度和可追溯性之规定，以改善健康和安全性。

Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety.

（5） 如有可能，应当考虑到为医疗器械制定的国际指导准则，特别是全球协调工作队及其后续行动即“ 国际医疗器械监管机构论坛（ IMDRF ）”，以便推动世界范围内利于提高安全防护标准以及促进贸易之相关法规的全球化进程，特别是关于唯一器械标识、通用安全与性能要求、技术文件、分类标准、符合性评估流程和临床证据等方面的规定。

To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

（6） 出于历史原因， 第 90/385/EEC 号指令所涵盖的有源植入式医疗器械以及第 93/42/EEC 号指令所涵盖的其他医疗器械通过另外两个单独的法律进行管控。为简化起见，经过若干次修订的两项指令均应替换为适用于除体外诊断医疗器械外所有医疗器械的单一立法法案。

For historical reasons, active implantable medical devices, covered by Directive 90/385/EEC, and other medical devices, covered by Directive 93/42/EEC, were regulated in two separate legal instruments. In the interest of simplification, both directives, which have been amended several times, should be replaced by a single legislative act applicable to all medical devices other than in vitro diagnostic medical devices.

(7) 本法规的适用范围应与其他相关产品的欧盟协调立法明确区分开， （如体外诊断医疗器械、 医药产品、 美容产品和食品）。因此，应对欧洲议会和委员会第 178/2002 号法规（ [1]）进行修订，将医疗器械排除在其范围之外。

The scope of application of this Regulation should be clearly delimited from other Union harmonisation legislation concerning products, such as in vitro diagnostic medical devices, medicinal products, cosmetics and food. Therefore, Regulation (EC) No 178/2002 of the European Parliament and of the Council (5) should be amended to exclude medical devices from its scope.

(8) 成员国有责任逐案例确认，各产品是否属于本法规范围。为确保所有成员国的相关判断力一致，特别是在灰区临界情况下，在咨询医疗器械协调小组（ MDCG ）后，应允许委员会主动或经成员国适时且有根据地请求，逐案决定某一具体产品、类别或产品组是否属于本法规适用范围。在审议涉及药品、人体组织和细胞、生物灭活

产品或食品之临界案例所辖产品之监管状况时，委员会应确保欧洲药品管理局、欧洲化学品管理局和欧洲食品安全局的适当咨询水平。

It should be the responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of this Regulation. In order to ensure consistent qualification decisions in that regard across all Member States, particularly with regard to borderline cases, the Commission should be allowed to, on its own initiative or at the duly substantiated request of a Member State, having consulted the Medical Device Coordination Group ('MDCG'), decide on a case-by-case basis whether or not a specific product, category or group of products falls within the scope of this Regulation. When deliberating on the regulatory status of products in borderline cases involving medicinal products, human tissues and cells, biocidal products or food products, the Commission should ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency and the European Food Safety Authority, as relevant.

(9) 由于在某些情况下医疗器械和美容产品难以区分，因此欧盟议会和理事会第 1223/2009 号法规（2）中也应加入对某一产品法规状况的欧盟范围统一决议。

Since in some cases it is difficult to distinguish between medical devices and cosmetic products, the possibility of taking a Union-wide decision regarding the regulatory status of a product should also be introduced in Regulation (EC) No 1223/2009 of the European Parliament and of the Council (6).

（10）药械组合类产品将按照本法规或欧洲议会和理事会第 2001/83/EC 号指令（[3]）进行管理。在涉及该药械组合产品的监管活动中，在上市前评估咨询及信息交换期间，两项立法法案应确保适当的相互关联。对于药械组合产品，应当在该医疗产品上市许可背景下，充分评估其是否符合本法规中规定的通用安全与性能要求。因此，应修订第 2001/83/EC 号指令。

Products which combine a medicinal product or substance and a medical device are regulated either under this Regulation or under Directive 2001/83/EC of the European Parliament and of the Council. (7) The two legislative acts should ensure appropriate interaction in terms of consultations during pre-market assessment, and of exchange of information in the context of vigilance activities involving such combination products. For medicinal products that integrate a medical device part, compliance with the general safety and performance requirements laid down in this Regulation for the device part should be adequately assessed in the context of the marketing authorisation for such medicinal products. Directive 2001/83/EC should therefore be amended.

（[1]）欧洲议会和理事会于 2002 年 1 月 28 日签发的第 178/2002 号（EC）法规规定了食品法的一般原则和要求，设立了欧洲食品安全局并制定了食品安全方面的程序（OJ L 31，1.2.2002，p.1）。

（[2]）欧洲议会和理事会于 2009 年 11 月 30 日签发的关于美容产品的第 1223/2009 号（EC）法规（OJ L 342，22.12.2009，p.59）。

（[3]）欧洲议会和理事会于 2001 年 11 月 6 日签发的关于人类药用产品社区规则的第 2001/83/EC 号指令（OJ L 311,28.11.2001，p.67）。

（11） 对于非活性或处理为非活性的人类来源组织或细胞衍生物制造的特定产品，欧盟立法特别是欧盟议会和理事会第 1394/2007 号法规（[1]）和第 2004/23/EC 号指令（[2]）并不完善。此类产品应属于本法规管辖范围，但前提是其应符合医疗器械的定义或受本法规管辖。

Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council (8) and Directive 2004/23/EC of the European Parliament and of the Council (9), is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such products should come under the scope of this Regulation, provided they comply with the definition of a medical device or are covered by this Regulation.

（12）本法规应涵盖制造商声称仅具有美容目的或另一种非医疗目的，但在功能和风险特征方面类似于医疗器械的特定产品组。为能使制造商证明此类产品的符合性，委员会应至少在应用风险管理时采用通用技术规范，并在必要时对安全性进行临床评价。这些通用技术规范应针对无医疗目的产品组制定，且不得用于具有医疗目的之类似器械的符合性评估。具有医疗和非医疗预期目的之器械应当同时满足具有和不具有预期医疗目的之器械相关要求。

Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.

（13） 由于第 90/385/EEC 和 93/42/EEC 号指令和本法规中明确排除含有人类或动物来源活组织或细胞的产品，应当澄清的是，含有或构成自其他来源活体生物物质或活体组织以实现或支持这些产品预期目的之产品也不在本法规管辖范围内。

As is the case for products that contain viable tissues or cells of human or animal origin, that are explicitly excluded from Directives 90/385/EEC and 93/42/EEC and hence from this Regulation, it should be clarified that products that contain or consist of viable biological materials or viable organisms of another origin in order to achieve or support the intended purpose of those products are not covered by this Regulation either.

（14） 欧洲议会和理事会第 2002/98/EC 号指令（[3]）设定的要求应当继续适用。

The requirements laid down in Directive 2002/98/EC of the European Parliament and of the Council (10) should continue to apply.

（15） 适用于器械的纳米材料风险和益处目前存在科学不确定性。为确保高水平的健康保护、货物自由流通和制造商的法律确定性，基于委员会第 2011/696/EU 号建议（[4]），有必要为纳米材料引入一个统一定义，这一定义应具有必要的灵活性，以使得这一定义适应科学和技术进展以及后续欧盟和国际层面的监管发展。在器械的设计和制造中，制造商在使用具有较高或中等体内照射可能的纳米颗粒时应特别注意，这些器械应接受最为严格的符合性评估程序。在法案试行期间对本法规中规定的相关要求的实施以及应用，应考虑相应科学委员会的科学意见。

There is scientific uncertainty about the risks and benefits of nanomaterials used for devices. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU (11), with the necessary flexibility to adapt that definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of devices, manufacturers should take special care when using nanoparticles for which there is a

high or medium potential for internal exposure. Such devices should be subject to the most stringent conformity assessment procedures. In preparation of implementing acts regulating the practical and uniform application of the corresponding requirements laid down in this Regulation, the relevant scientific opinions of the relevant scientific committees should be taken into account.

（16）欧洲议会和理事会第 2014/30/EU 号指令（ 5）所论述的安全问题属于本法规中规定的器械通用安全与性能要求的一部分。因此，本法规应被视为与该指令有关的特别法。

Safety aspects addressed by Directive 2014/30/EU of the European Parliament and of the Council (12) are an integral part of the general safety and performance requirements laid down in this Regulation for devices. Consequently, this Regulation should be considered a lex specialis in relation to that Directive.

（17）本法规应包括关于发射离子辐射的器械的设计和制造要求，而不影响寻求其他目标的理事会第 2013/59/Euratom 号指令（ [6]）的适用性。

This Regulation should include requirements regarding the design and manufacture of devices emitting ionizing radiation without affecting the application of Council Directive 2013/59/Euratom (13) which pursues other objectives.

（18）本法规应包括关于旨在防止职业伤害（包括辐射防护）的器械设计、安全与性能特性相关要求。

This Regulation should include requirements for devices' design, safety and performance characteristics which are developed in such a way as to prevent occupational injuries, including protection from radiation.

（[1]）欧洲议会和理事会于 2007 年 11 月 13 日签发的关于前沿疗法医药产品的第 1394/2007 号（EC）法规和修订了第 2001/83/EC 号指令和第 726/2004 号（EC）法规（ OJ L 324,10.12.2007， p. 121）。

（[2]）欧洲议会和理事会于 2004 年 3 月 31 日签发的关于制定人体组织和细胞捐赠、采购、检测、处理、保存、储存和分配质量和安全标准的第 2004/23/EC 号指令（ OJ L 102， 7.4.2004， p. 48）。

（[3]）欧洲议会和理事会于 2003 年 1 月 27 日签发的关于制定了人血和血液成分的收集、测试、处理、储存和分配的质量和安全标准的第 2002/98/EC 号指令（ OJ L 33， 8.2.2003， p. 30）。

（[4]）2011 年 10 月 18 日签发的关于纳米材料定义的委员会第 2011/696/EU 号建议（ OJ L 275,20.10.2011， p. 38）。

（[5]）2014 年 2 月 26 日欧洲议会和理事会第 2014/30/EU 号指令关于成员国有关电磁兼容性 (OJ L 96, 29.3.2014. p. 79)。

（[6]）2013 年 12 月 5 日签发的理事会第 2013/59/Euratom 号指令规定了有关因离子辐射接触所引起的危险防护的基本安全标准，并废除寻求其他目标的第 89/618/Euratom 号指令、第 90/641/Euratom 号指令、第 96/29/Euratom 号指令、第 97/43/Euratom 号指令和第 2003/122/Euratom 号指令 (OJ L 3, 17.1.2014, p. 1)。

（19） 有必要明确的是，当制造商的软件专用于医疗器械定义中所述的一种或多种医学目的时，软件本身可视为医疗器械，而用于一般目的的软件，即使在医疗保健环境中使用，或用于健康应用之软件，均不视为医疗器械。作为器械或附件之软件的资格评定不得依赖于这个软件和器械之间的物理位置或互连类型决定。

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

（20） 本法规中，关于器械本身、器械供应、经济运营商、使用者和具体过程、符合性评估、临床研究与证据、上市后监管、警戒和市场监管、标准和其他技术规范等定义应当符合 欧盟和国际上本领域的既定做法 ，以提高法律确定性。

The definitions in this Regulation, regarding devices themselves, the making available of devices, economic operators, users and specific processes, the conformity assessment, clinical investigations and clinical evaluations, post-market surveillance, vigilance and market surveillance, standards and other technical specifications, should be aligned with well-established practice in the field at Union and international level in order to enhance legal certainty.

(21) 应明确指出，通过欧洲议会和理事会第 2015/1535 号指令（[1]）中所规定的信息服务，向欧盟人员提供的器械以及在商业活动范围内用于为欧盟内人员提供诊断或治疗服务的器械，当在欧盟境内上市或提供服务时，必须符合本法规要求。

It should be made clear that it is essential that devices offered to persons in the Union by means of information society services within the meaning of Directive (EU) 2015/1535 of the European Parliament and of the Council (14) and devices used in the context of a commercial activity to provide a diagnostic or therapeutic service to persons within the Union comply with the requirements of this Regulation, where the product in question is placed on the market or the service is provided in the Union.

（22） 为认识到标准化在医疗器械领域中的重要作用，符合欧洲议会和理事会第 1025/2012 号法规（[2]）中规定的协调标准之相关证据，应是制造商证明其产品符合通用安全与性能要求以及其他法律要求（如本法规所述质量和风险管理）的手段。

To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council (15) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

(23) 欧洲议会和理事会第 98/79/EC 号指令（[3]）允许委员会对特定类别体外诊断医疗器械采用通用技术规范。在没有协调标准或协调标准不充分的地区，委员会应有权制定通用规范，以提供一种手段来符合本法规规定之通用安全与性能要求，以及临床研究和临床评估及 /或上市后跟踪等要求。

Directive 98/79/EC of the European Parliament and of the Council (16) allows the Commission to adopt common technical specifications for specific categories of in vitro diagnostic medical devices. In areas where no harmonised standards exist or where they are insufficient, the Commission should be empowered to lay down common specifications which provide a means of complying with the general safety and performance

requirements, and the requirements for clinical investigations and clinical evaluation and/or post-market clinical follow-up, laid down in this Regulation.

（24） 在咨询相关利益相关者并考虑欧洲和国际标准后，应制定通用规范（ “ CS ”）。

Common specifications (‘ CS’) should be developed after consulting the relevant stakeholders and taking account of European and international standards.

（25） 适用于器械的规则应酌情与“ 产品营销新立法框架 ”保持一致，其中包括欧洲议会和理事会第 765/2008 号法规（[4]），和欧洲议会和理事会第 768/2008/EC 号决议（ [5]）。

The rules applicable to devices should be aligned, where appropriate, with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 of the European Parliament and of the Council (17) and Decision No 768/2008/EC of the European Parliament and of the Council (18).

（26） 针对进入欧盟市场的产品，欧洲委员会第 765/2008 号法规规定的欧盟市场监管和控制规则，同样适用于本法规所涵盖的器械，但这不妨碍成员国自行选择主管机构来执行这些任务。

The rules on Union market surveillance and control of products entering the Union market laid down in Regulation (EC) No 765/2008 apply to devices covered by this Regulation which does not prevent Member States from choosing the competent authorities to carry out those tasks.

（27） 根据“ 产品营销新立法框架 ” ，在不影响本法规不同部分规定的具体义务的情况下， 明确规定不同经济运营商 （包括进口商和经销商）的一般义务，加强对本法规要求的理解，从而提高相关运营商的法规符合性。

It is appropriate to set out clearly the general obligations of the different economic operators, including importers and distributors, building on the New Legislative Framework for the Marketing of Products, without prejudice to the specific obligations laid down in the various parts of this Regulation, to enhance understanding of the requirements laid down in this Regulation and thus to improve regulatory compliance by the relevant operators.

（[1]）欧洲议会和理事会于 2012 年 10 月 25 日签发的有关欧洲标准化的第 1025/2012 号指令，修订了欧洲理事会第 89/686/EEC 和 93/15/EEC 号指令以及欧洲议会和理事会第 94/9/EC、94/25/EC、95/16/EC、97/23/EC、98/34/EC、2004/22/EC、2007/23/EC、2009/23/EC 和 2009/105/EC 号指令，并废除了欧洲理事会第 87/95/EEC 号决议和欧洲议会和理事会第 1673/2006/EC 号决议（ OJ L 316, 14.11.2012, p. 12）。

（[2]）欧洲议会和理事会于 2012 年 10 月 25 日签发的有关欧洲标准化的第 1025/2012 号指令，修订了欧洲理事会第 89/686/EEC 和 93/15/EEC 号指令以及欧洲议会和理事会第 94/9/EC、94/25/EC、95/16/EC、97/23/EC、98/34/EC、2004/22/EC、2007/23/EC、2009/23/EC 和 2009/105/EC 号指令，并废除了欧洲理事会第 87/95/EEC 号决议和欧洲议会和理事会第 1673/2006/EC 号决议（ OJ L 316, 14.11.2012, p. 12）。

（[3]）欧洲议会和理事会于 2015 年 9 月 9 日签发的关于在信息服务技术标准和法规领域提供信息的流程的第 2015/1535 号指令（ OJ L 241, 17.9.2015, p.1）。

（[4]）欧洲议会和理事会于 2008 年 7 月 9 日签发的关于与产品营销有关的认证和市场监管的要求的第 765/2008 号法规，废除了第 339/93 号法规 (OJ L 218, 13.8.2008,p. 30).

（5）欧洲议会和理事会于 2008 年 7 月 9 日签发的关于产品营销通用框架的第 768/2008/EC 号决议，并废除理事会第 93/465/EEC 号决议（OJ L 218, 13.8.2008, p. 82）。

（28） 就本法规而言，经销商的活动应视为包括获取、持有和供应器械。

For the purpose of this Regulation, the activities of distributors should be deemed to include acquisition, holding and supplying of devices.

（29） 制造商的一些义务，例如临床评价或警戒报告，仅为第 90/385/EC 和 93/42/EEC 号指令的附录中列出之内容，这些应纳入本法规颁布条款中，以便于应用。

Several of the obligations on manufacturers, such as clinical evaluation or vigilance reporting, that were set out only in the Annexes to Directives 90/385/EEC and 93/42/EEC, should be incorporated into the enacting provisions of this Regulation to facilitate its application.

（30） 卫生机构应可内部（而不是在工业规模上）制造、修改和使用器械，从而解决目标患者群体的具体需求，这些

需求往往无法通过市场上适当性能水平的等效医疗器械来满足。在这种情况下，适当的做法是在本法规中规定特定条款的豁免，这就是关于仅在卫生机构（含医院以及支持卫生保健系统和/或解决患者需求但可能不会直接治疗或照顾患者之实验室和公共卫生机构等）内部制造和使用器械的豁免条例，这样本法规就可以适当方式予以满足。应注意，卫生机构的概念不包括主要追求健康利益或健康生活方式的机构，例如健身房、水疗中心、健康与健身中心。因此，适用于卫生机构的豁免条例不适用于这些机构。

Health institutions should have the possibility of manufacturing, modifying and using devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market. In that context, it is appropriate to provide that certain rules of this Regulation, as regards medical devices manufactured and used only within health institutions, including hospitals as well as institutions, such as laboratories and public health institutes that support the healthcare system and/or address patient needs, but which do not treat or care for patients directly, should not apply, since the aims of this Regulation would still be met in a proportionate manner. It should be noted that the concept of ‘health institution’ does not cover estab primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centres. As a result, the exemption applicable to health institutions does not apply to such establishments.

（31） 鉴于自然人或法人可根据适用欧盟和国家法律，就缺陷器械造成的损害提出索赔，因此，可要求制造商采取适当措施，就其在第 85/374/EEC 号指令（[1]）规定的潜在责任提供足够的保险范围。这些措施应与器械的风险等级、类型和企业规模成比例。在本文中，还应规定有关主管机构向可能因缺陷器械而受伤人员提供信息的规则。

In view of the fact that natural or legal persons can claim compensation for damage caused by a defective device in accordance with applicable Union and national law, it is appropriate to require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability under Council Directive 85/374/EEC (19). Such measures should be proportionate to the risk class, type of device and the size of the enterprise. In this context, it is also appropriate to lay down rules concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

（32） 为确保批量生产的器械继续符合本法规的要求，并且将生产的器械的使用经验纳入生产过程中，所有制造商均应具备质量管理体系和上市后监管体系，此类系统应与上述器械的风险级别和分类对应。此外，为尽可能降低器械相关的风险或防止与之相关事故的发生，制造商应建立风险管理体系，以及报告事故和现场安全纠正措施的系统。

To ensure that devices manufactured in series production continue to be in conformity with the requirements of this Regulation and that experience from the use of the devices they manufacture is taken into account for the production process, all manufacturers should have a quality management system and a post-market surveillance system in place which should be proportionate to the risk class and the type of the device in question. In addition, in order to minimize risks or prevent incidents related to devices, manufacturers should establish a system for risk management and a system for reporting of incidents and field safety corrective actions.

（33） 风险管理体系应与器械的临床评估过程保持一致，并在该评估过程中反映，包括作为临床研究、临床评估和上市后临床跟踪的一部分需解决的临床风险。风险管理和临床评估过程应相互依存，并应定期更新。

The risk management system should be carefully aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.

（34） 应确保由符合最低资格条件的负责法规符合性的人员在制造商组织内进行医疗器械制造的监督和控制以及上市后监管和警戒活动。

It should be ensured that supervision and control of the manufacture of devices, and the post-market

surveillance and vigilance activities concerning them, are carried out within the manufacturer's organisation by a person responsible for regulatory compliance who fulfils minimum conditions of qualification.

(35) 对于欧盟以外的制造商，授权代表在确保此类制造商生产的器械符合性，以及作为其在欧盟建立的联系人方面发挥关键作用。鉴于这种关键作用，若欧盟以外的制造商未遵守其一般义务，出于执法目的，其授权代表依然应当对有缺陷的器械负法律责任。本法规规定的授权代表的法律责任并不影响第 85/374/EEC 号指令的规定，因此授权代表应对进口商和制造商承担连带责任。 应在书面指令中确定授权代表的职责。 鉴于授权代表的角色，应明确规定其应满足的最低要求，包括提供满足最低资格条件的人员的要求，此类资格条件应与制造商处负责法规符合性的人员的资格条件类似。

For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations. The liability of the authorised representative provided for in this Regulation is without prejudice to the provisions of Directive 85/374/EEC, and accordingly the authorised representative should be jointly and severally liable with the importer and the manufacturer. The tasks of an authorised representative should be defined in a written mandate. Considering the role of authorised representatives, the minimum requirements they should meet should be clearly defined, including the requirement of having available a person who fulfils minimum conditions of qualification which should be similar to those for a manufacturer's person responsible for regulatory compliance.

([1]) 欧盟委员会于 1985 年 7 月 25 日签发的关于其在涉及缺陷产品责任的成员国相似法律、法规和管理规定的第 85/374/EEC 号指令 (OJL210, 7.8.1985, p. 29)。

(36) 为确保经济运营商义务的法律确定性，有必要说明何时将经销商、进口商或其他人视为器械制造商。

To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

(37) 根据“欧盟运作条约（ TFEU ）”第 34 条的规定，（该规定以 TFEU 第 36 条规定的健康和安全保护需求以及知识产权保护需求带来的限制性规定为准）已经投放市场的产品的平行贸易是内部市场的一种合法贸易形式。但这一平行贸易原则的适用性受成员国的不同解释的制约。因此，应在本法规中特别规定重贴标和重包装的要求，同时考虑到其他相关行业的法院案例法（ [1]）和医疗器械领域的现有良好实践。

Parallel trade in products already placed on the market is a lawful form of trade within the internal market on the basis of Article 34 TFEU subject to the limitations arising from the need for protection of health and safety and from the need for protection of intellectual property rights provided for under Article 36 TFEU. Application of the principle of parallel trade is, however, subject to different interpretations in the Member States. The conditions, in particular the requirements for relabelling and repackaging, should therefore be specified in this Regulation, taking into account the case-law of the Court of Justice (20) in other relevant sectors and existing good practice in the field of medical devices.

(38) 一次性使用器械的再加工和进一步使用仅可在国家法律允许的情况下以及遵守本法规中规定的相关要求下进行。一次性使用器械的再加工者应视为再加工器械的制造商，并应承担本法规规定的制造商义不容辞的义务。尽管有上述规定，成员国有责任决议卫生机构内或通过代表该机构的外部再加工者对一次性使用器械再加工和再利用的义务可能与本法规中所述的制造商义务不同。原则上，仅当在机构内或通过代表该机构的外部再加工者对一次性器械再加工和重新利用符合已通过的 CS，或在缺乏 CS 时，符合相关协调标准和国家法规，才允许该偏差的存在。再加工此类器械应确保与相应未使用的一次性器械相同的安全和性能水平。

The reprocessing and further use of single-use devices should only take place where permitted by national law and while complying with the requirements laid down in this Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer described in this Regulation. In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

（39） 应给予植入器械患者以明确且容易获得的，足够识别所植入器械的基本信息，以及关于该器械的其他信息，包括任何必要的健康风险警戒或需采取的预防措施，例如关于其是否与某些诊断器械或用于安全控制的扫描仪兼容的指示。

Patients who are implanted with a device should be given clear and easily accessible essential information allowing the implanted device to be identified and other relevant information about the device, including any necessary health risk warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

（40） 一般来说，器械应具有 CE 标识，表明其符合本法规，以便其在欧盟内自由流通并根据其预期目的投入使用。成员国不得对符合本法规规定要求的器械，在其投放市场或投入使用方面制造障碍。不过，应允许成员国决定是否限制使用本法规未涵盖的任何特定类型的器械。

Devices should, as a general rule, bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the Union and be put into service in accordance with their intended purpose. Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation. However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation.

（41） 由于改进的事故报告、有针对性的现场安全纠正措施以及主管机构更好的监督机制，通过基于国际指导的唯一器械标识系统（ UDI 系统）实现的器械的可追踪性，应显著提高器械上市后安全相关活动的有效性。这归功于减少的医疗失误，以及对虚假器械的打击。 UDI 系统的应用还应改善卫生机构和其他经济运营商的采购和废物处置政策以及库存管理，并在可能的情况下，与这些设置中存在的其他验证系统兼容。

The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.

（42） UDI 系统应适用于除定制器械以外的投放于市场的所有器械，并基于国际公认的原则，包括与主要贸易伙伴相一致的定义。为使 UDI 系统及时起作用，以免影响本法规生效，应在本法规中做出详细规定。

The UDI system should apply to all devices placed on the market except custom-made devices, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation.

（43） 为保护公众健康，赋予患者和医疗保健专业人员自主权以及确保其能够做出明智的决定，为向监管决定制定提供一个稳妥的基础，确保为预期使用者提供的信息的透明度和充分性对于公众利益至关重要。

Transparency and adequate access to information, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

（1） 2011 年 7 月 28 日法院对 Orifarm 和 Paranova中案件： C-400/09 和 C-207/10, ECLI:EU:C:2011:519 的判决

（44） 为达成本法规目标，其中一个关键点是建立欧洲医疗器械数据库（Eudamed），该数据库应整合不同的电子系统，以核对和处理关于上市的体外诊断医疗器械以及相关经济运营商、符合性评定问题、公告机构、证书、临床研究、警戒和后市场监管等相关信息。数据库的目标是提高总体透明度，包括通过更好地为公众和卫生保健专业人员提供信息，以避免多重报告要求、加强成员国之间的配合、简化和促进经济运营商、公告机构或申办方和成员国之间的信息流通，以及成员国之间和欧盟委员会之间的信息流通。在内部市场中，只能在欧盟级别有效确保这一点，因此欧盟委员会应进一步开发和管理委员会第 2010/227/EU 号决议（[1]）设置的医疗器械数据库。

One key aspect in fulfilling the objectives of this Regulation is the creation of a European database on medical devices (Eudamed) that should integrate different electronic systems to collate and process information regarding devices on the market and the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals, to avoid multiple reporting requirements, to enhance coordination between Member States and to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission. Within the internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices set up by Commission Decision 2010/227/EU (21).

（45） 为促进欧洲医疗器械数据库（Eudamed）的运作，国际公认的医疗器械命名应免费提供给制造商和其他自然人或法人，且本法规要求相关人员必须使用该命名。此外，在合理可行的情况下，也应向其他利益相关者免费提供此类命名。

To facilitate the functioning of Eudamed, an internationally recognised medical device nomenclature should be available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. Furthermore, that nomenclature should be available, where reasonably practicable, free of charge also to other stakeholders.

（46） Eudamed 关于市场上的器械，相关经济运营商和证书的电子系统应确保公众充分了解欧盟市场上的器械。临床研究电子系统应作为工具，确保成员国之间合作，以及申办方能够在自愿基础上向若干成员国提交单项申请，并报告严重不良事件、器械缺陷和相关更新。电子警戒系统应确保制造商能够报告严重事件和其他异常事件，并支持主管机构协调此等事故和事件的评估。市场监管相关电子系统应作为主管机构之间进行信息交流的工具。

Eudamed's electronic systems regarding devices on the market, the relevant economic operators and certificates should enable the public to be adequately informed about devices on the Union market. The electronic system on clinical investigations should serve as a tool for the cooperation between Member States and for enabling sponsors to submit, on a voluntary basis, a single application for several Member States and to report serious adverse events, device deficiencies and related updates. The electronic system on vigilance should enable manufacturers to report serious incidents and other reportable events and to support the coordination of the evaluation of such incidents and events by competent authorities. The electronic system regarding market surveillance should be a tool for the exchange of information between competent authorities.

（47） 关于通过 Eudamed 电子系统核对和处理的数据，欧洲议会和理事会第 95/46/EC 号指令（[2]）适用于在成员国主管机构（特别是成员国指定的公共独立机构）的监督下，由成员国进行个人数据处理。欧洲议会和理事会第 45/2001 号法规（[3]）适用于在欧洲数据保护管理程序的监督下，由委员会在本法规框架内处理个人数据。根据第 45/2001 号指令，应指定委员会作为 Eudamed 及其电子系统的管理者。

In respect of data collated and processed through the electronic systems of Eudamed, Directive 95/46/EC of the European Parliament and of the Council (22) applies to the processing of personal data carried out in the Member States, under the supervision of the Member States' competent authorities, in particular the public independent authorities designated by the Member States. Regulation (EC) No 45/2001 of the European Parliament and of the Council (23) applies to the processing of personal data carried out by the Commission within the framework of this Regulation, under the supervision of the European Data Protection Supervisor. In

accordance with Regulation (EC) No 45/2001, the Commission should be designated as the controller of Eudamed and its electronic systems.

（48） 对于可植入器械和 III 类器械，制造商应在公开提供的文件中总结器械的主要安全与性能方面以及临床评估的结果。

For implantable devices and for class III devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.

（49） 器械安全和临床性能总结应特别包括在诊断或治疗选择中器械的地位，并考虑到在与诊断或治疗替代项相比时的器械临床评价，以及可能考虑该器械及其备选方案的具体条件。

The summary of safety and clinical performance for a device should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of that device when compared to the diagnostic or therapeutic alternatives and the specific conditions under which that device and its alternatives can be considered.

（50） 公告机构的正常运作对于确保高水平的健康和安全保护以及公民对系统的信心至关重要。因此，成员国根据详细和严格的标准对指定机构进行的指定和监测，应在欧盟级别实行控制。

The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

（51） 公告机构对制造商的技术文件的评估，特别是其临床评估文件，应由负责公告机构的主管机构进行严格评估。此类评估是一种基于风险的手段，用于监督和监测公告机构活动，评估时可采取相关文件抽样的方法。

Notified bodies' assessments of manufacturers' technical documentation, in particular documentation on clinical evaluation, should be critically evaluated by the authority responsible for notified bodies. That evaluation should be part of the risk-based approach to the oversight and monitoring activities of notified bodies and should be based on sampling of the relevant documentation.

（52） 应加强公告机构对制造商的监管，包括其进行突击飞行检查和对器械进行物理或实验室测试的权利和义务，以确保制造商在收到原始证书后持续合规。

The position of notified bodies vis-à-vis manufacturers should be strengthened, including with regard to their right and duty to carry out unannounced on-site audits and to conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

([1]) 委员会签发的关于设立医疗器械数据库的委员会第 2010/227/EU 号决议

([2]) 欧洲议会和理事会于 1995 年 10 月 24 日签发的关于保护个人在处理个人数据和数据自由流通方面的第 95/46/EC **22** 号指令 (OJ L281, 23.11.1995, p. 31)。

([3]) 欧洲议会和理事会于 2000 年 12 月 18 日签发的关于保护个人在欧共体机构和机构处理个人数据方面的欧洲理事会第 45/2001 号指令 **24**(OJ L8, 12.1.2001, p. 1)。

（53） 为提高国家主管机构监督公告机构的透明度，公告机构的主管机构应公布其用于指定和监测器械公告机构的国家评估监管措施的信息。根据良好的行政实践，主管机构应该及时更新这些信息，特别是反映上述流程的相关、重大或实质性变更。

To increase transparency with regard to the oversight of notified bodies by national authorities, the authorities responsible for notified bodies should publish information on the national measures governing the assessment, designation and monitoring of notified bodies. In accordance with good administrative practice, this information should be kept up to date by those authorities in particular to reflect relevant, significant or substantive changes to the procedures in question.

（54） 公告机构所在的成员国应负责执行本法规关于该公告机构的要求。

The Member State in which a notified body is established should be responsible for enforcing the requirements of this Regulation with regard to that notified body.

（55） 特别是考虑到成员国组织并提供保健服务和医疗护理的责任，允许其制定有关公告机构的其他要求，此类机构用于器械的符合性评估，并且基于本法规未规定问题的领域。规定的此等额外要求不会影响欧盟针对公告机构更为具体的横向欧盟立法和对公告机构的平等对待。

In view, in particular, of the responsibility of Member States for the organisation and delivery of health services and medical care, they should be allowed to lay down additional requirements on notified bodies designated for the conformity assessment of devices and established on their territory as far as issues that are not regulated in this Regulation are concerned. Any such additional requirements laid down should not affect more specific horizontal Union legislation on notified bodies and equal treatment of notified bodies.

（56） 对于旨在施用和 /或去除某种医疗产品的 III 类可植入器械和 IIb 类有源器械， 公告机构应有责任要求专家小组仔细审查其临床评估的评定报告 （某些特定情况除外） 。并且应当于这一专家小组符合性评估程序之后获得证书的器械通知主管机构。 通过分享临床方面的专业知识以及按已完成此咨询程序的器械分类建立 CS，临床评估相关专家小组的咨询结果应得出高风险医疗器械的协调评估。

For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinise their clinical evaluation assessment report. Competent authorities should be informed about devices that have been granted a certificate following a conformity assessment procedure involving an expert panel. The consultation of expert panels in relation to the clinical evaluation should lead to a harmonised evaluation of high-risk medical devices by sharing expertise on clinical aspects and developing CS on categories of devices that have undergone that consultation process.

（57） 对于 III 类和特定 IIb 类器械，制造商应在其临床评估和 /或调查之前，可自愿就其临床开发策略和临床研究提案咨询专家小组。

For class III devices and for certain class IIb devices, a manufacturer should be able to consult voluntarily an expert panel, prior to that manufacturer's clinical evaluation and/or investigation, on its clinical development strategy and on proposals for clinical investigations.

（58） 有必要根据国际惯例将器械划分为四个产品类别，特别是出于符合性评估流程考虑。基于人体脆弱性并考虑到与器械技术设计和制造相关的潜在风险的分类规则。 为保持与第 90/385/EEC 号指令中所规定相同的安全水平，有源植入式器械应属于最高风险类别。

It is necessary, in particular for the purpose of the conformity assessment procedures, to maintain the division of devices into four product classes in line with international practice. The classification rules, which are based on the vulnerability of the human body, should take into account the potential risks associated with the technical design and manufacture of the devices. To maintain the same level of safety as provided by

Directive 90/385/EEC, active implantable devices should be in the highest risk class.

（59） 旧框架下适用于侵入性器械的规则并未充分考虑到引入人体的特定器械侵入性水平和潜在毒性。针对在人体中吸收或局部扩展的物质或物质组合构成的器械，为获得基于风险的适当分类，必须针对此等器械引入特定分类规则。分类规则应当考虑到该器械在人体内或在人体上发挥作用的位置及将其引入或加以应用的位置，以及组成器械的这些物质还是这些物质在人体中的代谢产物是否会发生全身吸收。

Rules under the old regime applied to invasive devices do not sufficiently take account of the level of invasiveness and potential toxicity of certain devices which are introduced into the human body. In order to obtain a suitable risk-based classification of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body, it is necessary to introduce specific classification rules for such devices. The classification rules should take into account the place where the device performs its action in or on the human body, where it is introduced or applied, and whether a systemic absorption of the substances of which the device is composed, or of the products of metabolism in the human body of those substances occurs.

（60） 考虑到与这些器械有关的低水平脆弱性，作为一般规则，应由制造商单独负责执行有关 I 类器械的符合性评估程序。对于 IIa、IIb 和 III 类医疗器械，应当强制公告机构进行适当程度的参与。

The conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. For class IIa, class IIb and class III devices, an appropriate level of involvement of a notified body should be compulsory.

（61） 应进一步加强和简化器械符合性评估流程，同时应明确规定公告机构对其评估执行情况的要求，以确保公平竞争的环境。

The conformity assessment procedures for devices should be further strengthened and streamlined whilst the requirements for notified bodies as regards the performance of their assessments should be clearly specified to ensure a level playing field.

(62) 自由销售证书包含的信息，应该有助于使用 Eudamed ，以便获得器械的信息，无论器械是否上市，从市场撤出或召回，以及具备何种合格证。

It is appropriate that certificates of free sale contain information that makes it possible to use Eudamed in order to obtain information on the device, in particular with regard to whether it is on the market, withdrawn from the market or recalled, and on any certificate on its conformity.

（63） 为确保具有较高的安全与性能水平， 本法规中规定的通用安全与性能要求符合性的证明应基于以下临床数据：作为一般规则，对于 III 类器械和可植入性器械，此类数据应来自申办方所进行的临床研究。还可以由制造商和另一自然人或法人作为申办方负责开展此类临床研究。

To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation.

（64） 临床研究的规则应符合该领域成熟的指导原则，例如关于人类受试者医疗器械临床研究的临床试验质量管理规范（ISO 国际标准 14155:2011 ），以促使将在欧盟内进行的临床研究结果成为欧盟境外得到认可的文件规范，并促使根据国际准则在欧盟之外进行的临床研究结果可在欧盟内获得认可。此外，这些规则应符合世界医学协会《赫尔辛基宣言》关于涉及人类受试者医学研究伦理原则的最新版本。

The rules on clinical investigations should be in line with well-established international guidance in this field, such as the international standard ISO 14155:2011 on good clinical practice for clinical investigations of medical devices for human subjects, so as to make it easier for the results of clinical investigations conducted in the Union to be accepted as documentation outside the Union and to make it easier for the results of clinical investigations conducted outside the Union in accordance with international guidelines to be accepted within the Union. In addition, the rules should be in line with the most recent version of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

（65） 应由开展临床研究的成员国决定参与评估申请进行临床研究的适当管理机构，并组织伦理委员会在本法规设定的临床研究授权的时间期限内参与。这些决定属于各成员国的内部组织问题。在这种情况下，成员国应确保非专业人员，特别是患者或患者组织的参与。此外，其还应确保提供必要的专门知识。

It should be left to the Member State where a clinical investigation is to be conducted to determine the appropriate authority to be involved in the assessment of the application to conduct a clinical investigation and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical investigation as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. In that context, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available.

（66） 若在临床研究过程中，对受试者造成的伤害导致研究者或申办方承担民事或刑事责任，在这种情况下的法律责任条件，包括问题的因果关系和损害赔偿和制裁的水平，应该接受国家法律管辖。

Where, in the course of a clinical investigation, harm caused to a subject leads to the civil or criminal liability of the investigator or the sponsor being invoked, the conditions for liability in such cases, including issues of causality and the level of damages and sanctions, should remain governed by national law.

（67） 应在欧盟层面建立一个电子系统，以确保在可公开访问的数据库中记录和报告每一项临床研究。为保护“欧盟基本权利宪章”第 8 条规定的个人资料保护权益，不得在电子系统中记录参与临床研究的受试者的个人资料。为确保与医药产品临床试验领域的协同作用，临床研究的电子系统应与人用药品临床试验的欧洲数据库互通。 An electronic system should be set up at Union level to ensure that every clinical investigation is recorded and reported in a publicly accessible database. To protect the right to the protection of personal data, recognised by Article 8 of the Charter of Fundamental Rights of the European Union (‘the Charter no personal data of subjects participating in a clinical investigation should be recorded in the electronic system. To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use.

（68） 如需在一个以上的成员国进行临床研究，则申办方应提交单独申请，以便减少行政负担。为允许资源共享并确保用于研究器械以及临床研究的科学设计的卫生安全方面的一致性，这种单项申请的评估流程应便于在协调成员国指导下成员国之间协调。此等协调评估不得包括对临床研究的国家、地域和族群方面的评估，包括知情同意。自本法规施行之日起七年内，成员国应自愿参与协调评估。在这一时期结束后，所有成员国都有义务参与协调评估。委员会根据成员国之间自愿协调所取得的经验，应拟订有关协调评估流程的相关规定应用报告。若报告的结果是否定的，委员会应提交一份建议，延长协调评估流程中自愿参与的时间段。 Where a clinical investigation is to be conducted in more than one Member State, the sponsor should have the

possibility of submitting a single application in order to reduce administrative burden. In order to allow for resource-sharing and to ensure consistency regarding the assessment of the health and safety-related aspects of the investigational device and of the scientific design of that clinical investigation, the procedure for the assessment of such single application should be coordinated between the Member States under the direction of a coordinating Member State. Such coordinated assessment should not include the assessment of intrinsically national, local and ethical aspects of a clinical investigation, including informed consent. For an initial period of seven years from the date of application of this Regulation, Member States should be able to participate on a voluntary basis in the coordinated assessment. After that period, all Member States should be obliged to participate in the coordinated assessment. The Commission, based on the experience gained from the voluntary coordination between Member States, should draw up a report on the application of the relevant provisions regarding the coordinated assessment procedure. In the event that the findings of the report are negative, the Commission should submit a proposal to extend the period of participation on a voluntary basis in the coordinated assessment procedure.

（69） 申办方应向开展临床研究的成员国报告在临床研究期间发生的特定不良事件和器械缺陷。如认为有必要确保参与临床研究的受试者得到高水平保护，成员国应可以终止或暂停此等研究或撤销此等研究的授权。这些信息应该传达给其他成员国。 Sponsors should report certain adverse events and device deficiencies that occur during clinical investigations to the Member States in which those clinical investigations are being conducted. Member States should have the possibility of terminating or suspending the investigations or revoking the authorisation for those investigations, if considered necessary to ensure a high level of protection of the subjects participating in a clinical investigation. Such information should be communicated to the other Member States.

（70） 如适用，临床研究的申办人应在本法规规定的时间期限内编制一份预期使用者容易理解的临床研究研究摘要，连同临床研究报告一起提交。如因科学原因未能在规定的时间内提交结果摘要，申办人应说明理由，并说明何时提交结果。 The sponsor of a clinical investigation should submit a summary of results of the clinical investigation that is easily understandable for the intended user together with the clinical investigation report, where applicable, within the timelines laid down in this Regulation. Where it is not possible to submit the summary of the results within the defined timelines for scientific reasons, the sponsor should justify this and specify when the results will be submitted.

（71） 本法规应涵盖旨在证明器械符合性，以收集临床证据为目的的临床研究，并应同时规定有关其他类型医疗器械临床研究的伦理和科学评估的基本要求。 This Regulation should cover clinical investigations intended to gather clinical evidence for the purpose of demonstrating conformity of devices and should also lay down basic requirements regarding ethical and scientific assessments for other types of clinical investigations of medical devices.

（72） 无行为能力受试者、未成年人、孕妇和哺乳期妇女需要特殊保护措施。但需要由成员国确定无行为能力受试者和未成年人的法定代表人 ncapacitated subjects, minors, pregnant women and breastfeeding women require specific protection measures. However, it should be left to Member States to determine the legally designated representatives of incapacitated subjects and minors.

（73） 应遵守欧洲议会和理事会第 2010/63/EU 号指令（[1]）中所规定的动物实验领域的替换、减少和完善原则。特别是，应避免不必要的重复测试和研究。 The principles of replacement, reduction and refinement in the area of animal experimentation laid down in the Directive 2010/63/EU of the European Parliament and of the Council (24) should be observed. In particular, the unnecessary duplication of tests and studies should be avoided.

（74） 制造商应在售后阶段发挥积极作用，通过系统和积极地根据其器械售后体验收集信息，以更新其技术文件，并与负责警戒和市场监管活动的国家主管机构合作。为此，制造商应根据质量管理体系并基于上市后监管计划，建立一个综合的上市后监管体系。且应借助在上市后监管中收集的相关数据和信息，以及从任何执行的预防和 /或纠正措施中吸取的经验教训，更新技术文件的任何相关部分，如风险评估相关文件和临床评估，还应确保文件透明度。 Manufacturers should play an active role during the post-market phase by systematically and actively gathering information from post-market experience with their devices in order to update their technical documentation and cooperate with the national competent authorities in charge of vigilance and market surveillance activities. To this end, manufacturers should establish a comprehensive post-market surveillance system, set up under their quality management system and based on a post-market surveillance plan. Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

（75） 为更好地保障上市器械相关健康和安全问题，应当通过创建欧盟级别的中央门户网站报告严重事件和现场安全纠正措施，使得用于器械的电子警戒系统更有效。 In order to better protect health and safety regarding devices on the market, the electronic system on vigilance for devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

（76） 成员国应采取适当措施，提高医护专业人员、使用者和患者对报告事件的重要性的认识。应该鼓励医护专业人员、使用者和患者使用统一格式在国家级别报告可疑的严重事件。国家主管机构应通知制造商任何疑似严重事件，并且当制造商确认此等事故发生时，相关主管机构应确保采取适当的跟踪措施，以尽量避免此类事件的再次发生。 Member States should take appropriate measures to raise awareness among healthcare professionals, users and patients about the importance of reporting incidents. Healthcare professionals, users and patients should be encouraged and enabled to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers of any suspected serious incidents and, where a manufacturer confirms that such an incident has occurred, the authorities concerned should ensure that appropriate follow-up action is taken in order to minimise recurrence of such incidents.

（77） 应在国家级别评估报告的严重事件和现场安全纠正措施，但应确保在类似事件发生时进行协调，或者必须在多个成员国进行现场安全纠正措施，目的是共享资源并确保纠正措施的一致性。 The evaluation of reported serious incidents and field safety corrective actions should be conducted at national level but coordination should be ensured where similar incidents have occurred or field safety corrective actions have to be carried out in more than one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective action.

（78） 在事故调查背景中，主管机构应酌情考虑利益相关者（包括患者和医护专业人员组织和制造商协会）提供的信息和意见。 In the context of the investigation of incidents, the competent authorities should take into account, where appropriate, the information provided by and views of relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.

（79） 应清楚区分临床研究期间的严重不良事件或器械缺陷报告和器械投放市场后发生的严重事件报告，以避免重复报告。The reporting of serious adverse events or device deficiencies during clinical investigations and the reporting of serious incidents occurring after a device has been placed on the market should be clearly distinguished to avoid double reporting.

（80） 本法规应包含市场监管规则，以加强国家主管机构的权利和义务，确保市场监管活动的有效协调，并说明适用的流程。 Rules on market surveillance should be included in this Regulation to reinforce the rights and obligations of the national competent authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.

（81） 可能对风险利益分析产生重大影响，并且可能导致不可接受风险的，不严重或预期副作用事件，如数量或严

重程度出现显著增加，均应向主管机构报告，以允许其进行评估和采取适当的措施。Any statistically significant increase in the number or severity of incidents that are not serious or in expected side-effects that could have a significant impact on the benefit-risk analysis and which could lead to unacceptable risks should be reported to the competent authorities in order to permit their assessment and the adoption of appropriate measures.

（82）应当成立一个由成员国指派的专家（根据其在医疗器械（包括体外诊断医疗器械）领域中的职务和专长）组成的专家委员会，即医疗器械协调小组（MDCG），以完成本法规和欧洲议会和理事会第2017/746号法规（[2]）赋予该小组的使命，向委员会提供建议，以及协助委员会和成员国确保本法规的协调实施。MDCG应当能够建立其分小组，以便在医疗器械（包括体外诊断医疗器械）领域提供必要的、有见地的专门技术知识。在建立分小组时，应适当考虑在医疗器械领域中加入现有欧盟级别团体的可能性。An expert committee, the Medical Device Coordination Group (MDCG), composed of persons designated by the Member States based on their role and expertise in the field of medical devices including in vitro diagnostic medical devices, should be established to fulfil the tasks conferred on it by this Regulation and by Regulation (EU) 2017/746 of the European Parliament and of the Council (25), to provide advice to the Commission and to assist the Commission and the Member States in ensuring a harmonised implementation of this Regulation. The MDCG should be able to establish subgroups in order to have access to necessary in-depth technical expertise in the field of medical devices including in vitro diagnostic medical devices. When establishing subgroups, appropriate consideration should be given to the possibility of involving existing groups at Union level in the field of medical devices.

（[1]）欧洲议会和理事会于2010年9月22日签发的关于用于科学目的动物保护的第2010/63/EU号指令 (OJL276, 20.10.2010, p. 33)。

（[2]）欧洲议会和理事会于2017年4月5日签发的关于体外诊断医疗器械第2017/746号（EU）法规，废止了第98/79/EC号指令和委员会第2010/227/EU号决议（见本“官方公报”第176页）

（83）应由委员会根据最新的临床、科学或技术专业知识，委任专家委员会和专家实验室，以便向委员会、MDCG、制造商和与本法规实施有关的公告机构提供科学、技术和临床协助。此外，专家小组应履行对高风险器械的公告机构临床评估的评定报告提出自身意见的义务。Expert panels and expert laboratories should be designated by the Commission on the basis of their up-to-date clinical, scientific or technical expertise, with the aim of providing scientific, technical and clinical assistance to the Commission, the MDCG, manufacturers and notified bodies in relation to the implementation of this Regulation. Moreover, expert panels should fulfil the tasks of providing an opinion on clinical evaluation assessment reports of notified bodies in the case of certain high-risk devices.

（84）通过在协调机构的指导下的信息交流和协调评估，国家主管机构之间进行的更密切的协调，对于确保内部市场，特别是在临床研究和警戒领域的统一高水平的健康和安全保护至关重要。协调交流和评估的原则也应适用于本法规中说明的其他机构活动，例如公告机构名称，并应在器械的市场监管领域中鼓励使用该原则。活动的协作、协调和沟通也应在国家层级上引领更有效地利用资源和专门知识。Closer coordination between national competent authorities through information exchange and coordinated assessments under the direction of a coordinating authority is essential for ensuring a consistently high level of health and safety protection within the internal market, in particular in the areas of clinical investigations and vigilance. The principle of coordinated exchange and assessment should also apply across other authority activities described in this Regulation, such as the designation of notified bodies and should be encouraged in the area of market surveillance of devices. Joint working, coordination and communication of activities should also lead to more efficient use of resources and expertise at national level.

（85）委员会应向协调国家主管机构提供科学、技术和相应的后勤支持，并确保器械的监管制度在欧盟层级基于可靠的科学证据能够得以有效且统一地实施。The Commission should provide scientific, technical and corresponding logistical support to coordinating national authorities and ensure that the regulatory system for devices is effectively

and uniformly implemented at Union level based on sound scientific evidence.

（86） 欧盟及成员国应酌情积极参与医疗器械领域的国际监管合作，以促进医疗器械安全相关信息的交流，并促进国际监管准则的进一步发展，从而推动其他法规司法管辖区采用与本法规所规定卫生与安全保障水平同等的法规。 The Union and, where appropriate, the Member States should actively participate in international regulatory cooperation in the field of medical devices to facilitate the exchange of safety-related information regarding medical devices and to foster the further development of international regulatory guidelines that promote the adoption in other jurisdictions of regulations that lead to a level of health and safety protection equivalent to that set by this Regulation.

（87） 成员国应采取一切必要措施，确保本法规的规定得到执行，包括针对违反行为制定有效、相称和劝诫性的处罚。 Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by laying down effective, proportionate and dissuasive penalties for their infringement.

（88） 同时，本法规不得影响成员国对国家一级活动征收费用的权利，但成员国在决定相关费用级别和结构之前应通知欧盟委员会和其他成员国， 以确保透明度。 为进一步确保透明度， 应根据要求公开费用结构和级别。 Whilst this Regulation should not affect the right of Member States to levy fees for activities at national level, Member States should, in order to ensure transparency, inform the Commission and the other Member States before they decide on the level and structure of such fees. In order to further ensure transparency, the structure and level of the fees should be publicly available on request.

（89） 本法规尊重基本权利，并遵守《宪章》所认可的原则，尤其是人类尊严、人身完整性、个人资料的保护、艺术和科学自由、开展业务的自由和财产权。成员国应根据这些权利和原则应用本法规。 This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter and in particular human dignity, the integrity of the person, the protection of personal data, the freedom of art and science, the freedom to conduct business and the right to property. This Regulation should be applied by the Member States in accordance with those rights and principles.

（90） 根据 TFEU 第 290 条，应当授予委员会批准授权法案的权限，以便修订本法规的某些非必要规定。特别重要的是，委员会在其筹备工作期间，包括在专家层级上进行适当的咨询，且应根据 2016 年 4 月 13 日《改善的立法机构间协议》所规定的原则（ [1]）进行这些咨询。特别是，为确保平等参与制订授权法案，欧洲议会和理事会将与成员国专家同时收到所有文件，并且其专家可系统地参加委员会专家组会议，以讨论授权法案的制订。 The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in order to amend certain non-essential provisions of this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (26). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with preparation of delegated acts.

（91） 为确保执行本法规的条件一致，应向委员会授予执行权力。应根据欧洲议会和理事会第 182/2011 号法规（ [2]）行使这些权力。 In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (27).

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(1) OJ L123, 12.5.2016, p. 1.

(2) 欧洲议会和理事会 2011 年 2 月 16 日签发的关于规定行使这些权力及成员国管制委员会行使其执行权力机制的规则和一般原则的第 182/2011 号法规 (OJ L55, 28.2.2011, p.13)。

(92) 实施细则应借助咨询程序，其中规定了制造商安全与性能总结的数据要素形式，并建立了表述以及自由销售证书模式的形式与表述，因为实施细则具有程序性，并且不会直接对欧盟层级的卫生与安全产生影响。The advisory procedure should be used for implementing acts that set out the form and presentation of the data elements of manufacturers' summaries of safety and clinical performance, and that establish the model for certificates of free sale, given that such implementing acts are of a procedural nature and do not directly have an impact on health and safety at Union level.

(93) 若存在紧急理由，即涉及到欧盟领土扩张，而相关国家豁免适当符合性评估流程，则委员会应采取立即适用的实施细则。The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the extension to the territory of the Union of a national derogation from the applicable conformity assessment procedures, imperative grounds of urgency so require.

(94) 为使委员会能任命签发机构、专家小组和专家实验室，应授予委员会实施权限。In order to enable it to designate issuing entities, expert panels and expert laboratories, implementing powers should be conferred on the Commission.

(95) 为使经济运营商，特别是中小型企业、指定机构、成员国和委员会能够适应本法规引入的变化并确保其适当的应用，适当的做法是为这种适应和后期的组织安排提供充分的过渡期。但应当尽快实施法规中直接影响成员国和委员会的特定部分。特别重要的是，在本法规生效之日，根据新的要求指定足够数量的公告机构，以避免市场上医疗器械的任何短缺。尽管如此，在法规生效日期前，有必要根据本法规要求任命一个公告机构，但不得影响这些公告机构按照第 98/79/EC 号指令任命的有效性，并且不影响其按照该指令继续签发有效证书的权限，直至本法规生效。To allow economic operators, especially SMEs, notified bodies, Member States and the Commission to adapt to the changes introduced by this Regulation and to ensure its proper application, it is appropriate to provide for a sufficient transitional period for that adaptation and for the organisational arrangements that are to be made. However, certain parts of the Regulation that directly affect Member States and the Commission should be implemented as soon as possible. It is also particularly important that, by the date of application of this Regulation, a sufficient number of notified bodies be designated in accordance with the new requirements so as to avoid any shortage of medical devices on the market. Nonetheless, it is necessary that any designation of a notified body in accordance with the requirements of this Regulation prior to the date of its application be without prejudice to the validity of the designation of those notified bodies under Directives 90/385/EEC and 93/42/EEC and to their capacity to continue issuing valid certificates under those two Directives until the date of application of this Regulation.

(96) 为确保顺利过渡至器械和证书注册的新规定，按照本法规，向在欧盟层级别设置的电子系统提交相关信息的义务（若已根据计划开发了相应的 IT 系统）应当在本法规适用日期后的 18 个月内完全有效。在此过渡期内，第 90/385/EEC 和 93/42/EEC 号指令的某些条款应继续有效。但根据这两项法规在欧盟层级设立的相关电子系统中注册的经济运营商和指定机构应视为符合成员国根据规定所采取的注册要求，以避免多次注册。In order to ensure a smooth transition to the new rules for registration of devices and of certificates, the obligation to submit the relevant information to the electronic systems set up at Union level pursuant to this Regulation should, in the event that the corresponding IT systems are developed according to plan, only become fully effective from 18 months after the date of application of this Regulation. During this transitional period, certain provisions of Directives 90/385/EEC and 93/42/EEC should remain in force. However, in order to avoid multiple registrations, economic operators and notified bodies who register in the relevant electronic systems set up at Union level pursuant to this Regulation should be considered to be in compliance with the registration requirements adopted by the Member States pursuant to those provisions.

（97） 为使 UDI 系统顺利引入，将 UDI 载体加在器械标签上义务的生效时机还应当在本法规生效日期之后一年至五年之间完成，具体取决于相关器械的类别。 In order to provide for a smooth introduction of the UDI system, the moment of application of the obligation to place the UDI carrier on the label of the device should vary from one to five years after the date of application of this Regulation depending upon the class of the device concerned.

（98） 应废除第 90/385/EEC 号和第 93/42/EEC 号指令，以确保只有一套规则适用于医疗器械投放市场及本法规所涉及相关问题。制造商依然有义务为其投放市场的器械提供相关文件，而制造商和成员国依然有义务按照该指令开展已投放市场器械的监管活动。虽然应当由成员国决定如何组织监管活动，但建议成员国使用与报告依照本法规投放市场之器械相同的工具来报告使用依照该指令投放市场的器械。此外，为确保从旧框架顺利过渡到新框架，恰当的做法是规定欧盟委员会第 207/2012 号法规（[1]）和欧盟委员会第 722/2012 号法规（[2]）应持续有效并继续适用，除非并直至其被执行委员会根据本法规通过的实施细则废除。 Directives 90/385/EEC and 93/42/EEC should be repealed to ensure that only one set of rules applies to the placing of medical devices on the market and the related aspects covered by this Regulation. Manufacturers' obligations as regards the making available of documentation regarding devices they placed on the market and manufacturers' and Member States' obligations as regards vigilance activities for devices placed on the market pursuant to those Directives should however continue to apply. While it should be left to Member States to decide how to organise vigilance activities, it is desirable for them to have the possibility of reporting incidents related to devices placed on the market pursuant to the Directives using the same tools as those for reporting on devices placed on the market pursuant to this Regulation. It is furthermore appropriate, in order to ensure a smooth transition from the old regime to the new regime, to provide that Commission Regulation (EU) No 207/2012 (28) and Commission Regulation (EU) No 722/2012 (29) should remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

Decision 2010/227/EU adopted in implementation of those Directives and Directive 98/79/EC should also remain in force and continue to apply until the date when Eudamed becomes fully functional. Conversely, no such maintenance in force is required for Commission Directives 2003/12/EC (30) and 2005/50/EC (31) and Commission Implementing Regulation (EU) No 920/2013 (32).

（[1]）委员会于 2012 年 3 月 9 日签发的关于医疗器械使用电子机构的委员会第 207/2012 号法规 (OJ L72, 10.3.2012, p. 28) 。

（[2]） 委员会于 2012 年 8 月 8 日签发的关于在委员会关于有源植入式医疗器械和医疗器械第 90/385/EEC 和 93/42/EEC 指令规定要求特殊要求的委员会第 722/2012 号法规。

在欧洲医疗器械数据库完全启用日之前，在实施这些指令和第 98/79/EC 号指令时所通过的第 2010/227/EU 号决议应继续有效并继续适用。相反，委员会第 2003/12/EC（[1]）和 2005/50/EC 号指令（[2]）和委员会第 920/2013 号实施法规（[3]）无需维持效力。

（99） 本法规的要求应适用于自本法规生效之日起投放市场或投入使用的所有器械。但为提供平稳过渡，应能够允许器械自该日期起的有限期限内，根据第 90/385/EEC 或 93/42/EEC 号指令颁发的有效证书投放市场或投入使用。 The requirements of this Regulation should be applicable to all devices placed on the market or put into service from the date of application of this Regulation. However, in order to provide for a smooth transition it should be possible, for a limited period of time from that date, for devices to be placed on the market or put into service by virtue of a valid certificate issued pursuant to Directive 90/385/EEC or pursuant to Directive 93/42/EEC.

(100) 欧洲数据保护主管根据欧洲委员会第 45/2001 号法规第 28（2）条发表了意见（[4]）。The European Data Protection Supervisor has given an opinion (33) pursuant to Article 28(2) of Regulation (EC) No 45/2001.

（101） 出于本法规的目标，即确保医疗器械境内市场的顺利运转并确保医疗器械的高质量和安全性，因此若患者、使用者及其他人员的卫生与安全得到高水平的保护，无法由成员国充分实现，且由于规模和效果，可更好地在欧盟层级中实现时，欧盟可根据《欧盟条约》第 5 条规定的辅助性原则采取措施。按照该条款中规定的比例原则，本法规将不会超过实现该目标所需范围。 Since the objectives of this Regulation, namely to ensure the smooth functioning of the internal market as regards medical devices and to ensure high standards of quality and safety for medical devices, thus ensuring a high level of protection of health and safety of patients, users and other persons, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

已经通过本法规： HAVE ADOPTED THIS REGULATION

CHAPTER I

第 I 章

范围及定义

SCOPE AND DEFINITIONS

第 1 条

Article 1

主题与范围

Subject matter and scope

1. 本法规规定了有关欧盟境内供人类使用的医疗器械极其附件的市场投放、市场提供或投入使用方面的规则。本法规也适用于在欧盟进行的有关该医疗器械及其附件临床研究。 This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.

2. 本法规还应适用于自根据第 9 条通过的通用规范适用之日起，附录 XVI 所列并无预期医疗目的产品组，并考虑到基于类似技术的目前最高水平，特别是适用于具有医疗目的类似器械的现有协调标准。该附录 XVI 中所列产品组的通用规范应至少解决适用于如该产品组附录 I 中所列风险管理应用，及必要时，针对安全性的临床评价。

应在 2020 年 5 月 26 日通过强制性的通用技术规范。此类规范应自其生效日的六个月后或自 2020 年 5 月 26 日起适用，以最迟发布者为准。 his Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI, taking into account the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology. The common specifications for each of the groups of products listed in Annex XVI shall address, at least, application of risk management as set out in Annex I for the group

of products in question and, where necessary, clinical evaluation regarding safety.
The necessary common specifications shall be adopted by 26 May 2020. They shall apply as from six months after the date of their entry into force or from 26 May 2020, whichever is the latest.

尽管存在第 122 条规定，根据第 93/42/EEC 号指令为附录 XVI 所涵盖的医疗器械的产品符合相关成员国措施仍应继续有效，直至第一子段所要求的该产品组的相关通用规范适用日为止。 Notwithstanding Article 122, Member States' measures regarding the qualification of the products covered by Annex XVI as medical devices pursuant to Directive 93/42/EEC shall remain valid until the date of application, as referred to in the first subparagraph, of the relevant common specifications for that group of products.

本规范也适用在欧盟进行的有关第一子段所述产品的临床研究。 This Regulation also applies to clinical investigations conducted in the Union concerning the products referred to in the first subparagraph.

3. 具有医疗和非医疗预期目的器械应逐渐的满足适用于具有预期医疗目的器械要求和适用于无预期医疗目的器械的那些要求。 Devices with both a medical and a non-medical intended purpose shall fulfil cumulatively the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.

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(1) 2003 年 2 月 3 日委员会签发的关于医疗器械第 93/42/EEC 号指令范围内乳房植入物的再分类的委员会第 2003/12/EC 号指令 (OJ L28, 4.2.2003, p. 43)。

(2) 2005 年 8 月 11 日委员会签发的关于医疗器械第 93/42/EEC 号指令范围内髋、 膝盖和肩膀关节替换的委员会第 2005/50/EC 号指令（OJ L210, 12.8.2005, p. 41 ）。

(3) 2013 年 9 月 24 日委员会签发的关于根据关于有效可植入医疗器械委员会第 90/385/EEC 号指令和关于医疗器械第 93/42/EEC 号指令指定和监督公告机构的委员会第 920/2013 号实施条例 (OJ L253, 25.9.2013, p. 8). 。

(4) OJ C358, 7.12.2013, p. 10.

4. 就本法规而言，根据第 2 段，本法规适用的附录 XVI 所列医疗器械、医疗器械附录及医疗产品均在下文中简称为“ 器械 ”。For the purposes of this Regulation, medical devices, accessories for medical devices, and products listed in Annex XVI to which this Regulation applies pursuant to paragraph 2 shall hereinafter be referred to as ‘ devic

5. 如从其特性和风险方面来看，考虑到投放市场的具有医疗目的器械与不具医疗目的产品之间的相似性具有正当理由，则委员会应有权根据第 115 条借助增加新产品组以通过授权法案从而修订附录 XVI 中的清单，以便保护使用者或其他人员的健康和安全或所涉及公共卫生的其他方面。 Where justified on account of the similarity between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list in Annex XVI, by adding new groups of products, in order to protect the health and safety of users or other persons or other aspects of public health.

6. 本法规不适用于： This Regulation does not apply to:

（a）欧盟第 2017/746 号法规所涵盖的体外诊断医疗器械；

（b）如第 2001/83/EC 号指令第 1 条第 2 点中所定义的医疗产品。在确定产品是否属于第 2001/83/EC 号指令或本法规的范围时，应特别考虑产品的主要作用模式。

（c） 欧洲委员会第 1394/2007 号法规所涵盖的前沿疗法医药产品；

（d） 人类血液或血液制品、人源的血浆或血细胞，或者在投放市场或投入使用时，包含此类血液制品、血浆或细胞的器械，但本条第 8 段所述的器械除外；

（e） 欧洲委员会第 1223/2009 号法规所涵盖的美容产品；

（f） 动物源的移植器官、组织或细胞或其衍生产品，或含有或由其组成的产品；但本法规适用于使用非活性或活性动物来源的组织或细胞或其衍生产品制造而成的器械。

（g） 第 2004/23/EC 号指令所涵盖的人源移植器官、组织或细胞或其衍生产品，或含有或由其组成的产品；但器械适用于使用活性或非活性人源组织或细胞的衍生产品制造而成的器械；

（h）除了（ d)、（f）和（ g）点中述及的那些含有或包括活性生物物质或活菌体（包括活体微生物、细菌、真菌或病毒）以实现或支持产品预期用途的产品；

（i）第 178/2002 号（ EU）法规所涵盖的食品。

(a) in vitro diagnostic medical devices covered by Regulation (EU) 2017/746;

(b) medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC. In deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product;

(c) advanced therapy medicinal products covered by Regulation (EC) No 1394/2007;

(d) human blood, blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells, except for devices referred to paragraph 8 of this Article;

(e) cosmetic products covered by Regulation (EC) No 1223/2009;

(f) transplants, tissues or cells of animal origin, or their derivatives, or products containing or consisting of them however this Regulation does apply to devices manufactured utilising tissues or cells of animal origin, or th derivatives, which are non-viable or are rendered non-viable;

(g) transplants, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, or produ containing or consisting of them; however this Regulation does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable;

(h) products, other than those referred to in points (d), (f) and (g), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria, fungi or viruses in order to achieve support the intended purpose of the product;

(i) food covered by Regulation (EC) No 178/2002.

7. 在投放市场或投入使用时，作为欧盟第 2017/746 号法规第 2 条第 2 点所界定的体外诊断医疗器械的一个整体部分任何器械，应受第 2017/746 号法规管制。本法规的要求应适用于体外诊断医疗器械部件。 Any device which, when placed on the market or put into service, incorporates as an integral part an in vitro diagnostic medical device as defined in point 2 of Article 2 of Regulation (EU) 2017/746, shall be governed by this Regulation. The requirements of Regulation (EU) 2017/746 shall apply to the in vitro diagnostic medical device part of the device.

8. 若器械在投放市场或投入使用时，包含某一种必不可少的物质，而该物质若单独使用将被视为第 2001/83/EC 号指令第 1 条第 2 点所界定的医药产品，其中包括该指令第 1 条第 10 点所定义的人体血液或血浆来源的药物制品，并且具有辅助器械的作用，该器械应根据本法规进行评估和授权。

但是，若该物质的作用是主要作用，而不是辅助该器械的作用，则综合产品应由适用的欧洲议会和理事会第 2001/83/EC 号指令或第 726/2004 号法规（[1]）管制。在这种情况下，本法规附录 I 中规定的相关通用安全与性能要求应适用于器械部件的安全与性能。 Any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the device, shall be assessed and authorised in accordance with this Regulation. However, if the action of that substance is principal and not ancillary to that of the device, the integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004 of the European Parliament and of the Council (34), as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

9. 若器械适用于第 2001/83/EC 号指令第 1 条第 2 点定义的药品，则该器械应受本法规管制，且不影响该指令的规定以及欧洲委员会关于药品的第 726/2004 号法规。 Any device which is intended to administer a medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC shall be governed by this Regulation, without prejudice to the provisions of that Directive and of Regulation (EC) No 726/2004 with regard to the medicinal product.

但若该器械预期与药品一起使用，且该药品与器械组成一个整体的方式投放市场，该产品专用于给定的组合并且不可重复使用，则产品应按第 2001/83/EC 号指令或欧洲委员会第 726/2004 号法规管制。在这种情况下，本法规附录 I 中规定的相关通用安全与性能要求应适用于器械部件的安全与性能。 However, if the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC or Regulation (EC) No 726/2004, as applicable. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part of the single integral product are concerned.

([1]) 2004 年 3 月 31 日欧洲议会和理事关于规定授权和监督人用和兽用医疗产品和成立欧洲药品管理局的共同体程序 (OJ L136, 30.4.2004, p. 1)。

10. 当器械在投放市场或投入使用时，包含必不可少的人体非活性组织或细胞或其衍生物，且具有辅助器械的作用，则应按照本法规对该器械进行评估和授权。在这种情况下，第 2004/23/EC 号指令中规定的捐赠、采购和测试规定应适用。 Any device which, when placed on the market or put into service, incorporates, as an integral part, non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device shall be assessed and authorised in accordance with this Regulation. In that case, the provisions for donation, procurement and testing laid down in Directive 2004/23/EC shall apply.

但若这些组织或细胞或其衍生物的作用是主要的，而不是辅助器械的作用，且产品不受欧洲委员会第 1394/2007 号法规管制，则该产品应受第 2004/23/EC 号指令管制。在这种情况下，本法规附录 I 中规定的相关通用安全与性能要求应适用于器械部件的安全与性能。 However, if the action of those tissues or cells or their derivatives is principal and not ancillary to that of the device and the product is not governed by Regulation (EC) No 1394/2007, the product shall be governed by Directive 2004/23/EC. In that case, the relevant general safety and performance requirements set out in Annex I to this Regulation shall apply as far as the safety and performance of the device part are concerned.

11. 本法规属于第 2014/30/EU 号指令第 2(3)条所辖欧盟特别立法。

This Regulation is specific Union legislation within the meaning of Article 2(3) of Directive 2014/30/EU.

12 存在指令中所述相关风险的情况下，作为欧洲议会和欧洲委员会关于机械的第 2006/42/EC 号指令（[1]）第 2 段第 a 点所列器械同样应满足该指令附录 I 中规定的基本卫生与安全要求，这些要求比本法规附录 I 第 II 章所规定的通用安全与性能要求更为具体。 Devices that are also machinery within the meaning of point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (35) shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation.

13. 本法规不影响第 2013/59/Euratom 号指令的应用。 This Regulation shall not affect the application of Directive 2013/59/Euratom

14. 本法规不影响成员国在本法规未涵盖的方面限制使用任何特定类型器械的权利。 This Regulation shall not affect the right of a Member State to restrict the use of any specific type of device in relation to aspects not covered by this Regulation.

15 本法规不影响有关卫生服务和医疗保健的组织、交付或融资的国家法律，例如要求某些器械只能以医疗处方提供，要求只有某些卫生专业人员或卫生护理机构可分发或应用某些器械，或者其应用必须伴随特定的专业咨询。

This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or healthcare institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

16. 本法规不限制新闻自由或媒体中的言论自由，只要这些自由在欧盟和成员国中得到保障，特别是《欧洲联盟基本权利宪章》第 11 条。 Nothing in this Regulation shall restrict the freedom of the press or the freedom of expression in the media in so far as those freedoms are guaranteed in the Union and in the Member States, in particular under Article 11 of the Charter of Fundamental Rights of the European Union.

第 2 条 Article 2

定义 Definitions

就本法规而言，应适用以下定义： For the purposes of this Regulation, the following definitions apply:

“医疗器械”是指由制造商单独使用或组合用于人体的以下一种或多种特定医疗目的任何仪器、设备、器具、软件、植入物、试剂、材料或其他物品：

– 对疾病的诊断、预防、监护、预测、预后、治疗或缓解；

– 对损伤或残疾的诊断、监控、治疗、缓解、补偿

– 解剖、生理或病理过程或状态的研究、替代、调节，

– 通过对来自人体的样本（包括器官、血液、捐献的组织）进行体外检测来提供信息。

– 其效用主要通过物理等方式获得， 不是通过药理学、免疫学或者代谢的方式获得，或者虽然有这些方式参与但是只起辅助作用；

以下产品也应视为医疗器械：

– 具有控制或支持用途的器械。

– 专门用于器械的清洁、消毒或灭菌，如第 1（4）条和本点第一子段第中所述

‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

— and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

（1） 2006 年 5 月 17 日欧洲议会和理事会签发的关于机械和修订第 95/16/EC 号指令的第 2006/42/EC 号指令 (OJ L157, 9.6.2006, p. 24) 。

(2) “医疗器械附件”是指制造商计划将其与一个或几个特定医疗器械一起使用，使该医疗器械可按照其预期用途进行使用， 或特定或直接辅助医疗器械来实现其预期用途的功能， 但其不是医疗器械的物件； ‘accessory for a medical device’ means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

(3) “定制器械”是指根据国家法律授权的任何人员的书面处方，通过该人员的专业资格知识而专门制造的器械，具有特有的设计特性，计划专用于特定患者，并专门满足个人条件和需要。 ‘custom- made device’ means any device specifically made in accordance with a written prescription of any person authorised by national

law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs

但需要通过调整以满足任何专业使用者特殊要求的大规模生产的器械，且根据经授权人员的书面处方通过工业生产过程大规模生产的器械不得视为定制器械； However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;

(4) “有源器械”是指任何器械，其操作依靠除了人体或通过重力产生能量源外的能量来源，并且其通过改变该能量的密度或转换该能量而发挥作用。用于在有源器械和患者间传输能量、物质或其他元素而无任何显著变化的器械不得视为有源器械。 ‘active device’ means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

软件应被视为有源器械； Software shall also be deemed to be an active device

(5) “可植入器械”指任何器械，包括部分或完全被吸收的器械，其通过临床干预用于 ‘implantable device’ means any device, including those that are partially or wholly absorbed, which is intended:

– 完全植入人体或 to be totally introduced into the human body, or

– 取代上表皮或眼睛表面， to replace an epithelial surface or the surface of the eye,

并且在手术后保持原样。 任何用于通过临床干预部分引入人体并且在手术后保持原样至少 30 天的器械也应视为可植入器械； by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device;

(6) “侵入式器械”是指通过人体自然通道或人体表面穿入人体的任何器械； ‘invasive device’ means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

(7) “通用器械组”是指具有相同或类似预期用途或相同技术的一组器械，允许以不反映特定属性的通用方式对其进行分类； generic device group’ means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) “一次性使用器械”是指在单次使用且仅用于一个人的器械。 ‘single-use device’ means a device that is intended to be used on one individual during a single procedure;

（9） “伪造器械”是指其标识和/或来源和/或 CE 标识证书或与 CE 标识程序相关文件为虚假伪造的器械。此定义不包含无意的不合规，并且不影响知识产权的侵犯。 ‘falsified device’ means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;

（10） “器械包”是指包装在一起并投放市场用于特定医疗目的产品的组合； ‘procedure pack’ means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

（11） “系统”是指包在一起或未包在一起的，用于相互连通或组合以实现特定医疗目的产品组合； system’ means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose;

（12） “预期用途” 是指制造商根据标签、 说明书、 促销或销售材料或声明中所提供的数据在临床评价中指定的用途； intended purpose ’ means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

（13） “标签”是指出现在器械本身， 或在各装置包装上或多个器械包装上的印刷文字或图形类的信息； ‘label ’ means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

（14） “说明书”是指由制造商提供，用以告知器械使用者该产品的预期用途、正确使用方法以及注意事项的信息。 ‘instructions for use ’ means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken;

（15） “唯一器械标识” （UDI）是指通过国际认可的器械标识和编码标准创建的一系列数字或字母数字字符，并允许明确识别市场上的特定器械； Unique Device Identifier ’(‘UDI’) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

（16） “非活性”是指没有代谢或繁殖的潜力； ‘non-viable ’ means having no potential for metabolism or multiplication;

（17） “衍生物”是指通过生产过程从人或动物组织或细胞提取的“非细胞物质” 。在这种情况下，用于制造器械的最终物质不得含有任何细胞或组织； derivative ’ means a ‘non-cellular substance ’ extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues;

（18） “纳米材料” 是指含有颗粒的一种天然或人工制造材料 （），该材料以游离状态或作为一种集合体或作为一种结块存在，粒径分布中颗粒到达 50%或更多，具有一个或多个外部尺寸，尺寸范围介于 1 nm-100 nm 之间。 nanomaterial ’ means a natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm;

具有一个或多个低于 1nm 的外部尺寸的富勒烯、石墨烯薄片和单壁碳纳米管应视为纳米材料； Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall also be deemed to be nanomaterials;

（19） “颗粒”，就第 (18)点中纳米材料的定义而言，是指具有确定物理边界的一小块物质； particle ’, for the purposes of the definition of nanomaterial in point (18), means a minute piece of matter with defined physical boundaries;

(20) “附聚物”，就第 (18)点中纳米材料的定义而言，是指弱结合的颗粒或聚集体的集合，其中外表面积与各个成分的表面积总和相同； agglomerate ’, for the purposes of the definition of nanomaterial in point (18), means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

(21) “聚集体”，就第 (18)点中纳米材料的定义而言，是指包含强结合的颗粒或熔合颗粒； ‘aggregate ’, for the purposes of the definition of nanomaterial in point (18), means a particle comprising of strongly bound or fused particles;

(22) “性能”是指器械实现制造商要求的预期用途的能力； ‘performance ’ means the ability of a device to achieve its

intended purpose as stated by the manufacturer;

(23) “风险”是指危害发生概率和危害严重性的组合。 risk ’ means the combination of the probability of occurrence of harm and the severity of that harm;

(24) “利益风险评估”是指在根据制造商规定的预期用途使用器械时，与预期用途相关的所有利益和风险评估的分析；benefit- risk determination ’ means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

(25) “相容性”是当根据其预期用途与一个或多个其他器械一起使用时， 器械（包括软件）的能力： compatibility ’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to:

（a） 执行而不失去或损害执行预期使用目的的能力，和 /或 perform without losing or compromising the ability to perform as intended, and/or

（b） 整合和 /或操作而不需要修改或调整器械任何部分的功能，和 /或 integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

（c） 在没有冲突 /干扰或不良反应的情况下一起使用的能力。 be used together without conflict/interference or adverse reaction.

(26) “互操作性”是指来自相同制造商或不同制造商的两个或更多器械 （包括软件） 的以下能力 ‘ interoperability ’ is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:

（a） 交换信息并能通过所交换的信息来为执行指定功能而不改变数据内容的能力，和 /或 exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or

（b） 相互通信的能力，和 /或 communicate with each other, and/or

（c） 按照预期用途一同运作 work together as intended 。

(27) “在市场上可获得” 是指在商业活动过程中于欧盟市场上分配、 消费或使用的任何器械 （除了用于研究器械外）的任何供应 （不论其是付费或免费供应） ；‘ making available on the market ’ means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(28) “市场投放”是指在欧盟市场上首次提供除研究器械以外的器械； ‘ placing on the market ’ means the first making available of a device, other than an investigational device, on the Union market

(29) “投入使用”是指器械（用于研究的器械除外）可供最终使用者使用以准备在欧盟市场上首次用于其预期使用目的的阶段； ‘ putting into service ’ means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

(30) “制造商”是指制造或全面翻新器械或具有设计、制造或全面翻新的器械并以其名称或商标销售该器械的自然人或法人。 ‘ manufacturer ’ means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

(31) “全面翻新”，基于制造商的定义， 是指已投放市场或投入使用的器械全面翻新， 或者利用已使用的器械制造新器械，以使其符合本法规，并赋予翻新的器械新的寿命； ‘ fully refurbishing ’, for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with

the assignment of a new lifetime to the refurbished device;

(32) “授权代表”是指在欧盟境内确定的任何自然人或法人，其收到并接受位于欧盟以外的制造商的书面授权，代表该制造商按照本法规对制造商所规定的义务要求所进行的一切行动； ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

(33) “进口商”是指在欧盟内确定的任何自然人或法人，其来自器械投放于欧盟市场的第三国； ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market;

(34) “经销商”是指供应链中除了制造商或进口商外的任何自然人或法人，其负责从器械投放市场到投入使用的整个过程； distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(35) “经济运营商”是指制造商、授权代表、进口商、经销商和第 22(1)和 22(3)条的所指人员； economic operator’ means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

(36) “卫生机构”是指以护理抑或治疗疾病或促进公众健康为目的组织； health institution’ means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

(37) “使用者”是指使用器械的任何医护专业人员或非专业人员； ‘user’ means any healthcare professional or lay person who uses a device;

(38) “非专业人员”是指未在相关医疗卫生或医学学科领域接受正规教育的个人； ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

(39) “再处理”是指在使用过的器械上进行的处理过程，以便允许其安全再利用，包括清洁、消毒、灭菌和相关程序，以及测试和恢复所用器械的技术和功能安全性； ‘reprocessing’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

(40) “符合性评估” 是指证明本法规中与器械相关的要求是否得到满足的过程； ‘conformity assessment’ means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;

（41） “符合性评估机构”是指执行第三方符合性评估活动的机构，活动包括评估、检查、认证和审核； conformity assessment body’ means a body that performs third -party conformity assessment activities including calibration, testing, certification and inspection;

（42） “公告机构”是指根据本法规指定的符合性评估机构； notified body’ means a conformity assessment body designated in accordance with this Regulation

（43） “CE 合格标识”或“ CE 标识”是指制造商为表明该器械符合本法规和其他适用的欧盟协调立法对其标识规定的适用要求而使用的标识； ‘CE marking of conformity’ or ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

（44） “临床评价”是指，连续地产生、收集、分析和评估与器械有关的临床数据的一个系统化的流程，目的是为验证按照制造商所规定的预期用途使器械用器械的安全性及性能包括临床收益； ‘clinical evaluation’ means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

（45） “临床研究”是指对一个或多个受试者进行的任何系统性研究，以评估器械的安全性及产品性能； ‘clinical investigation’ means any systematic investigation involving one or more human subjects, undertaken to

assess the safety or performance of a device;

（46） “研究器械”是指在临床研究中评估的任何器械；‘investigational device’means a device that is assessed in a clinical investigation;

（47） “临床研究计划”是指说明临床研究的理论、目标、设计、方法、监察、统计方法、组织和施行方案的文件；‘clinical investigation plan’means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

（48） “临床数据”是指与器械使用产生以及源于以下内容的安全或性能有关的信息：clinical data’means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

– 有关器械的临床研究 clinical investigation(s) of the device concerned, ,
– 器械（指可证明其与待考核器械具有等效性的器械）的临床研究或在科学文献中报告的其他研究, clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
– 在同行评审的科学文献中发表的关于所讨论器械或可以证明与该器械等效的另一种器械的其他临床经验报告 reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
– 来自上市后监管体系的其他临床数据, 特别是上市后临床跟踪； clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

（49） “申办方”是指负责启动、管理临床研究和设立临床研究融资的任何个人、公司、机构或组织；‘sponsor’means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation;

（50） “受试者”是指参与临床研究的个体；‘subject’means an individual who participates in a clinical investigation;

（51） “临床证据”是指关于足够数量和质量的器械的临床数据和临床评价结果，以允许在制造商按预期使用时，对器械是否安全并达到预期临床受益进行符合性评估；‘clinical evidence’means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

（52） “临床性能”是指器械因技术或功能特性包括诊断特性产生的任何直接或间接医学效应，以在使用时器械时实现其制造商要求的预期用途从而使临床患者受益的能力的；‘clinical performance’means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

（53） “临床受益”是指器械对个体健康的积极影响，被指定为有意义、可测量、与患者相关的临床结果，包括与诊断相关的结果或对患者管理或公共卫生的积极影响；‘clinical benefit’means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

（54） “研究员”是指负责在临床研究现场进行临床研究的个人；‘investigator’means an individual responsible for the conduct of a clinical investigation at a clinical investigation site;

（55） “知情同意”是指受试者在参与临床试验前，被告知与其参与的临床研究所有相关问题后自由和自愿地表达他或她参与特定临床研究的意愿，或者对于未成年人和无行为能力的受试者，在临床研究中应包括其法定代表的授权书或协议；‘informed consent’means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation

that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

（56） “伦理委员会”是指根据成员国的法律在该成员国设立的一个独立机构，其有权依据本法规要求对临床试验提出意见，该意见应同时考虑到非专业人员，特别是患者或患者组织的意见； ‘ethics committee’ means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;

（57） “不良事件”是指在临床研究的背景中，无论是否与研究器械有关，在受试者、使用者或其他人中的任何不良医学事件， 非预期的疾病或损伤或任何不利的临床征兆， 包括异常的实验室发现； ‘adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;

（58） “严重不良事件” 是指导致以下任一状况的任何不良事件： ‘serious adverse event’ means any adverse event that led to any of the following:

（a） 死亡 death, ,

（b） 严重损害受试者的健康，导致以下情况 serious deterioration in the health of the subject, that resulted in any of the following: ：

(i) 危及生命的疾病或损伤； life-threatening illness or injury,

(ii) 造成身体结构或身体机能的永久损伤， permanent impairment of a body structure or a body function,

(iii) 住院或延长患者的住院时间； hospitalisation or prolongation of patient hospitalisation,

(iv) 医疗或手术干预来防止危及生命的疾病或损伤或身体结构或身体机能的永久损伤， medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) 慢性疾病， chronic disease,

（c） 胎儿窘迫、 胎儿死亡或先天性身体或精神损伤或先天缺陷； foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

（59） “器械缺陷”是指研究器械的标识、质量、耐久性、可靠性、安全性或性能的任何缺陷，包括制造商提供的信息中的故障、使用错误或缺陷； ‘device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer

(60) “上市后监管”是指制造商与其他经济运营商合作开展的所有活动，目的旨在建立并保持最新的系统化程序，以主动收集和总结从已投放市场、市场上可获得或投入使用的器械获得的经验，以确定是否需要立即采取任何必要的纠正或预防措施； ‘postmarket surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

（61） “市场监管”是指主管当局执行的活动和采取的措施，目的旨在检查和确保器械符合相关欧盟协调立法中规定的要求， 并且不危害健康、 安全或公共利益保护的任何其他方面； ‘market surveillance’ means the activities

carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

（62） “召回”是指旨在收回已提供给最终使用者器械所采取任何措施； ‘recall’ means any measure aimed at achieving the return of a device that has already been made available to the end user;

（63） “撤回”是指旨在防止供应链中的器械进一步在市场上供应的任何措施； ‘withdrawal’ means any measure aimed at preventing a device in the supply chain from being further made available on the market;

（64） “事件”是指市场上可获得的器械特性或性能的任何故障或劣化事件，包括由于人机工程学特征、制造商提供的信息中的任何不足以及任何不期望的副作用而造成的使用错误； ‘incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect;

（65） “严重不良事件”是指直接或间接导致、有可能导致或可能会导致以下任一状况的任何事件： ‘serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:

（a） 患者、使用者或其他人员死亡； the death of a patient, user or other person,

（b） 患者、使用者或其他人员健康状态的暂时性或永久性严重恶化； the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

（c） 严重公众健康威胁； a serious public health threat;

（66） “严重公众健康威胁”是指可能导致死亡风险、健康状态的严重恶化或导致需要对其立即采取补救措施，可能会导致人类较高发病率或死亡率或在特定地点和时间出现不寻常或意外情况的严重疾病的任何事件； ‘serious public health threat’ means an event which could result in imminent risk of death, serious deterioration person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

（67） “纠正措施”是指为消除潜在或实际不符合法规要求项目或其他不良情况而采取的措施； ‘corrective action’ means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

（68） “现场安全性纠正措施”是指制造商出于技术或医疗原因采取的纠正措施，目的是防止或降低发生与市场上供应的器械有关的严重不良事件的风险； ‘field safety corrective action’ means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

（69） “现场安全通知”是指制造商向使用者或客户发送的与现场安全性纠正措施相关的信件； ‘field safety notice’ means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

（70） “协调标准” 是指欧盟第 1025/2012 号法规第 2 条第（1）（c）点规定的欧盟标准； ‘harmonised standard’ means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012;

（71） “通用规范 （CS）”是指一套技术或临床要求，而非对器械的生产或体系提供符合法律要求的标准。 ‘common specifications (CS)’means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.

第 3 条 Article 3

特定定义修改 **Amendment of certain definitions**

委员会有权根据第 115 条采取授权行为，以基于技术和科技进步并考虑到商定的欧盟和国际层级的定义，调整第 2 条（18）点所述纳米材料的定义和（ 19）、（20）和（ 21）点的相关定义。

The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend the definition of nanomaterial set out in point (18) and the related definitions in points (19), (20) and (21) of Article 2 in the light of technical and scientific progress and taking into account definitions agreed at Union and international level.

第 4 条 Article 4

产品监管现状 **Regulatory status of products**

1. 在不影响第 2001/83/EC 号指令第 2(2)条的情况下，经成员国充分证实的请求，委员会在咨询根据本法规第 103 条成立的医疗器械协调小组（ MDCG ）后，应通过实施细则，确定特定产品或某类或某组产品属于医疗器械或“医疗器械的附件”的定义。应按照本法规第 114(3)条中述及的审查规程通过这些实施细则。 Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation （‘ MDCG’), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of ‘ medical device ’ or ‘ accessory for a medical device ’. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.

2. 欧盟委员会也可在咨询 MDCG 后，自行决议是否通过实施细则确定本条第 1 段所述的问题。应根据第 114（3）条所述检查程序采用这些实施方案。 The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

3. 欧盟委员会应确保成员国之间共享体外诊断试剂、医疗器械、药产品、人体组织和细胞、美容剂、灭菌剂、食品和其他产品 （如必要） 领域的专业知识， 以便确定产品或产品类别或产品组的监管状态。 The Commission shall ensure that Member States share expertise in the fields of medical devices, in vitro diagnostic medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products, in order to determine the appropriate regulatory status of a product, or category or group of products.

4. 在审议涉及药品、人体组织和细胞、生物杀灭产品或食品所辖产品监管状况时，委员会应确保欧洲药品管理局（EMA）、欧洲化学品管理局（ ECHA ）和欧洲食品安全管理局（ EFSA）具有的一定的能力可提供咨询。 When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant.

第 II 章 CHAPTER II

器械的上市供应和投入使用、经济运营商的义务、再处理、 CE 标识、自由流通

MAKING A VAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING , CE MARKING , FREE MOVEMENT

第 5 条 Article 5

投放市场和投入使用 Placing on the market and putting into service

1. 仅当器械遵循本法规适当供应并根据其预期用途正确安装、维护和使用时，该器械方可投放市场或投入使用。 A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. 器械应满足相关载于附录 I 的通用安全与性能要求，同时考虑到其预期用途。 A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. 通用安全与性能要求的符合性证明应包含符合第 61 条的临床评价。 Demonstration of conformity with the

general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

4. 应将在卫生机构制造和使用的器械视为已投入使用。 Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5. 除了附录 I 中的相关通用安全与性能要求外，此法规的规定不适用于仅在欧盟卫生机构内部生产和使用的器械，前提是能够满足以下条件： With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

（a）该器械不被转移到另一个法律实体， the devices are not transferred to another legal entity,

（b）在质量管理体系中制造和使用器械， manufacture and use of the devices occur under appropriate quality management systems,

（c） 卫生机构在其文件中证明，市场上的相似器械无法达到目标患者群体需要的适当性能水平。 the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

（d） 卫生机构向其主管机构提供了这些器械的使用信息，包括生产、更新和使用的理由； the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

（e） 卫生机构拟定了一份公之于众的声明，包含了 the health institution draws up a declaration which it shall make publicly available, including ：

(i) 制造器械的卫生机构的地址和名称； the name and address of the manufacturing health institution;

(ii) 识别器械的详细信息； the details necessary to identify the devices;

(iii) 一份器械满足本法规附录 I 中设定的通用安全和性能要求的声明，未满足相关要求时，声明中还有相关合理理由， a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

（f） 卫生机构拟定文件，以此了解生产设施、制造过程、该器械的设计和性能数据，包括预期用途，足够详细，以使主管机构确定载列于本法规附录 I 通用安全和性能要求得到满足； the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

（g） 卫生机构会采取一切必要措施，以确保所有器械均按照（ f）点所述文件中的规定进行生产； the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

（h） 卫生机构会审查器械的临床使用体验，并采取一切必要的纠正措施。 the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

成员国可要求卫生机构向主管机构提供更多在其领土上生产和使用器械的相关信息。各成员国有权限制特殊型号器械的生产和使用，且应允许成员国检查卫生机构的活动。 Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions

本段规定不适用于按工业规模生产的器械。 This paragraph shall not apply to devices that are manufactured on an

industrial scale

6. 委员会可以通过实施细则来确保附录 I 统一得到应用，且该法案应可达到解决误解和实际应用上的问题的程度。此外，应按照第 114(3)条中述及的审查规程通过这些实施细则 . In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 6 条 Article 6

远程销售 Distance sales

1. 如欧盟第 2015/1535 号指令第 1(1)条（b）点所规定的，通过资讯社会服务提供给位于欧盟境内的自然人或法人的器械应遵循本法规的要求。 A device offered by means of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to a natural or legal person established in the Union shall comply with this Regulation

2. 在不违反国家立法机构对医疗专业活动所做规定的情况下，对于未上市但用于商业活动的器械，无论有偿还是无偿使用，只要是按欧盟第 2015/1535 号指令第 1(1)条（ b）点所规定的通过资讯社会服务或其他沟通媒介直接或间接提供给位于欧盟境内的自然人或法人的诊断服务和治疗服务，均应遵循本法规要求。

Without prejudice to national law regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.

3. 应主管机构要求，根据第 1 段提供器械或根据第 2 段提供服务的自然人或法人应遵守器械的相关要求，提供一份相关器械的欧盟符合性声明。

Upon request by a competent authority, any natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.

4. 如欧盟第 2015/1535 号指令第 1(1)条（b）点所规定，成员国可以保护公众健康为由，要求资讯社交服务供应商停止其活动。

A Member State may, on grounds of protection of public health, require a provider of information society services, as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535, to cease its activity.

第 7 条 Article 7

索赔 Claims

在贴标签、使用说明、提供服务、投入使用和为器械做广告时，禁止使用误导使用者或患者器械预期使用目的、安全性和性能的文字、名称、商标、图片、图形或其他类似标识，误导手法有：

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by

(a) 说明该器械不具备的功能和特性； ascribing functions and properties to the device which the device does not have;

(b) 制造器械有或无的治疗或诊断功能或其他功能和特性的假象； creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) 未告知使用者或患者器械预期用途相关风险； failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) 符合性评估完成后， 表明器械的用途与预期用途不符。 suggesting uses for the device other than those stated to

form part of the intended purpose for which the conformity assessment was carried out.

第 8 条 Article 8

使用协调标准 Use of harmonised standards

1. 符合相关协调标准或相关这些标准的部分的器械，其附于欧盟官方公报中的参考资料应符合本法规的全部和部分要求。

Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

根据本法规，第一子段也应适用于经济运营商或申办方根据本法规应履行的系统要求或过程要求，包括质量管理体系、风险管理、上市后监管体系、临床研究、临床评价或上市后临床跟踪（ PMCF）的相关要求。 The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up （‘ PMCF’）

本法规引用的协调标准参考资料应理解为与发表在欧盟官方公报上的参考资料一致。 References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the Official Journal of the European Union.

2. 本法规中协调标准的引用，还包括根据欧洲药典详述方面，尤其是在手术缝合线方面以及在含有此类医疗产品的器械中用的医药产品与材料之间的相互作用方面的惯例，采用的欧洲药典专著，但前提是这些专著已发表在欧盟官方公报上。

References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided that references to those monographs have been published in the Official Journal of the European Union.

第 9 条 Article 9

通用规范 Common specifications

1. 在不影响第 1（2）条和第 17（5）条以及其中规定的限期的情况下，若未统一标准存在，或相关协调标准不充分，或者需要解决公共卫生问题，则委员会在咨询 MDCG 后，可就载列于附录 I 的通用安全与性能要求、载列于附录 II 和 III 的技术文件、载列于附录 XIV 的临床评价及上市后的临床跟踪或者载列于附录 XV 有关临床研究的要求，借助实施细则，采用通用规范（ CS）。根据第 114(3)条中所述的审查程序，应通过实施细则来采纳 CS。

Without prejudice to Article 1(2) and 17(5) and the deadline laid down in those provisions, where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns, the Commission, after having consulted the MDCG , may, by means of implementing acts, adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annexes II and III, the clinical evaluation and post-market clinical follow-up set out

in Annex XIV or the requirements regarding clinical investigation set out in Annex XV . Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. 符合第 1 段中所述的 CS 的器械应视为符合本法规中的相关 CS 要求（全部或部分） 。

Devices that are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or the relevant parts of those CS.

3. 制造商应遵守第 1 段中所述的 CS，除非其能证明其已采纳的方法能够确保等效的安全性和性能水平。

Manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

4. 尽管有第 3 段的要求，附录 XVI 所列产品的制造商应遵循这些产品相关的 CS。

Notwithstanding paragraph 3, manufacturers of products listed in Annex XVI shall comply with the relevant CS for those products.

第 10 条 Article 10

制造商的义务 General obligations of manufacturers

1. 当将其器械投放市场或投入使用时，制造商应确保所有器械均按本法规的要求进行设计和生产。

When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

2. 制造商应如附录 I 第 3 节所述，确立、记录、实施和维护风险管理体系。

Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

3. 制造商应按照载于第 61 条和附录 XIV 规定的要求进行临床评价，包括 'PMCF' 。

Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.

4. 除了定制器械外器械的制造商应拟定并更新这些器械的技术文件。该技术文件应允许评定该器械与本法规要求的符合性。该技术文件应包括附录 II 和 III 列出的要点。

Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.

鉴于技术进展和附录 II 和附录 III，根据第 115 条修订内容，委员会有权批准授权法案。

The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.

5. 定制器械制造商应拟定、更新并向主管机构提供符合附录 XIII 第 2 节的文档。

Manufacturers of custom-made devices shall draw up, keep up to date and keep available for competent authorities documentation in accordance with Section 2 of Annex XIII.

6. 若适用的符合性评估流程证明器械符合适用的要求，则器械（非定制或研究用器械）制造商应根据第 19 条的要求制定欧盟符合性声明，并根据第 20 条的要求附上标有符合性的 CE 标识。 Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, shall draw up an EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.

7. 制造商应遵守第 27 条中所述的 UDI 系统相关义务，以及第 29 和 31 条所述的注册义务。 Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

8. 制造商应保存技术文件、欧盟符合性声明、适用时还有根据第 56 条颁发的相关证书及修订件和补充件的副本，在欧盟符合性声明中所涵盖的最后器械上市后，该文档应至少向主管机构开放 10 年。若为可植入器械，周期应至少为最后器械已投放市场后的 15 年。 Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

经主管机构要求，制造商应提供完整的技术文件或总结。 Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

为使授权代表能够完成第 11（3）条中所述的任务，在欧盟境外注册营业的制造商应确保授权代表有永久可用的必要文档。 A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

9. 制造商应确保采取必要程序，以使批量生产符合本法规的要求。应及时充分考虑器械设计或特性的更改和协调标准或器械符合性所声明的 CS 的更改。器械（非研究用器械）制造商应以最有效的及根据风险等级和器械类别的方式确立、记录、实现、维护、不断更新和不断改善一个能确保器械符合本法规规定的质量管理体系。 Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

质量管理体系包括制造商组织的所有处理流程、程序和器械质量的组成部分。它管理着结构、职责、程序、流程和管理资源，以贯彻所需的原则和行动，以遵守本法规的规定。 The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

质量管理体系应至少解决以下方面的问题：

The quality management system shall address at least the following aspects:

(a) 法规符合性战略，包括符合性评估流程的符合性和系统所涵盖的器械的变更管理程序；

a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) 确定适用的通用安全与性能要求，寻找可选择的解决这些要求的方法；

identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) 管理责任； responsibility of the management;

(d) 资源管理，包括选择和管理供应商和分包商；

resource management, including selection and control of suppliers and sub-contractors;

(e) 附录 I 第 3 节中规定的风险管理； risk management as set out in Section 3 of Annex I;

(f) 临床评价，根据第 61 条和附录 XIV 的规定，包括 PMCF；clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) 产品实现规划，包括规划、设计、研发、生产和服务提供； product realisation, including planning, design, development, production and service provision;

(h) 根据第 27（3）条规定验证所有相关器械的 UDI 分配，确保根据第 29 条提供的信息的一致性和有效性；verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

(j) 根据第 83 条的要求，建立、实施和维护上市后监管体系； setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) 与主管机构、公告机构、其他经济运营商、客户和/或其他利益相关人沟通； handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) 警戒情况下的严重事件和现场安全纠正措施的报告流程； processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) 纠正措施和预防措施的管理及其有效性的验证； management of corrective and preventive actions and verification of their effectiveness;

(m) 产品的监督和测量流程，数据分析和产品改进。 processes for monitoring and measurement of output, data analysis and product improvement.

10. 器械制造商应根据第 83 条的规定实施并不断更新上市后监管体系。

Manufacturers of devices shall implement and keep up to date the post-market surveillance system in accordance with Article 83.

11. 制造商应确保器械附有附录 I 第 23 节规定的信息，且信息应采用器械上市国（同时也是成员国）指定的欧盟官方语言编写。标签上的详情应不可拭除、容易识别并且使用者和患者能够清楚理解。

Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

12. 认为或有理由认定其投放于市场或交付使用的器械未遵照本法规的制造商，应立即采取必要纠正措施使器械符合要求，并适时撤回或召回。其应通知所述的器械经销商，并适时通知授权代表和相应进口商。 Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

如器械出现严重风险，制造商应立即通知各成员国主管机构哪些器械可用，如适用，公告机构根据第 56 条为器械颁发证书，特别是未遵守要求及其采取的纠正措施。 Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56, in particular, of the non-compliance and of any corrective action taken.

13. 制造商应有一套如第 87 和 88 条所述，记录和报告意外事件和现场安全的纠正措施系统。 Manufacturers shall

have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88.

14. 制造商应根据主管机构要求，由相关成员国用官方欧盟语言确定，提供其一切必要信息和文档以证明器械符合要求。如制造商有其注册的营业地点，成员国主管机构可要求制造商免费提供器械样品。如不可行，则授予其器械访问权。制造商应与主管机构合作，按其要求，采取纠正措施以消除风险。如不可行，则降低其已投放市场或投入使用的器械所导致的风险。 Manufacturers shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable, grant access to the device.

Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

若制造商合作失败或提供的信息和文档不完整或不正确，则主管机构为确保保护公众卫生和患者安全，将采取一切必要措施禁止或限制在国内市场采购该器械，从该市场撤回或召回器械直至制造商与主管机构合作，或提供完整且正确的信息。 If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until the manufacturer cooperates or provides complete and correct information.

如主管机构认为或有理由认定器械已造成损害，应当根据要求，协助提供有关第一子段的信息和文档，在不影响数据保护规则，除非在披露凌驾性公众利益，且不影响知识产权保护的前提下，给潜在受伤患者或使用者、患者或使用者的所有权继承人、 受伤患者或使用者的医疗保险公司或经受伤患者， 或使用者影响的其他第三方。主管机构无须遵守第三子段中有关第一子段所述的信息披露一般是按法律程序进行的义务。 If a competent authority considers or has reason to believe that a device has caused damage, it shall, upon request, facilitate the provision of the information and documentation referred to in the first subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's successor in title, the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph where disclosure of the information and documentation referred to in the first subparagraph is ordinarily dealt with in the context of legal proceedings.

15. 如制造商将其器械交由其他法人或自然人设计和制造，则按照第 30（1）条， 其法人或自然人的身份信息将成为待提交信息的一部分。 Where manufacturers have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1).

16. 自然人或法人可按照适当欧盟和国家法律，要求对由缺陷器械引起损害进行赔偿。

Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.

根据风险等级、器械类别和企业规模，制造商应采取措施并根据国家法律在不影响更多防护措施的情况下，根据第 85/374/EEC 号指令，按照其潜在责任提供足够财政保障。

Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

第 11 条 Article 11

授权代表 Authorised representative

1. 当所有成员国器械制造商均未确立时，若制造商指定唯一授权代表，则器械只能投放于欧盟市场。 Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

2. 委任应构成授权代表的授权书，只有在授权代表书面许可时，且至少在相同种类的所有器械有效时，才有效。 The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

3. 授权代表应执行其和制造商间授权同意的指定任务。授权代表应根据要求向主管机构提供授权书副本。 The authorised representative shall perform the tasks specified in the mandate agreed between it and the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request.

授权书应要求且制造商应协助授权代表至少执行相关器械的以下任务： The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

(a) 核实已拟定符合性和技术文件的欧盟声明, 且在适当时核实制造商已实施适当符合性评估流程。 verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) 保留一份可用的技术文件、欧盟符合性声明副本。如适用，保留一份包括所有修订和补充的相关证书副本，并按照第 56 条，在第 10(8)条指定时期，由主管机构签发； keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

(c) 遵守第 31 条规定的注册义务，并核实该制造商已遵守第 27 和 29 条规定的注册义务； comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29;

(d) 响应主管机构的要求，提供所有必要信息和文档，采用相关成员国确定的欧盟官方语言，证明器械符合要求； in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

(e) 向制造商转达，授权代表具有其经营样品注册地成员国主管机构的所有要求，或访问器械，并核实主管机构收到样品或可访问器械； forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

(f) 配合主管机构采取的任何预防或纠正措施以消除或, 如不可行, 降低由器械导致的风险； cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) 立即通知制造商来自医护专业人员、患者和使用者与有关指定器械可疑事件的投诉和举报； immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

(h) 如制造商违反本法规义务，则终止授权书。 terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

4. 本条第 3 段所述指的授权书不得包括第 10（1）、（2）、（3）、（6）、（7）、（9）、（10）、（11）和（ 12）所规定制造商的义务授权。 The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).

5. 在不影响本条第 4 段的情况下， 当所有成员国的制造商都未确立， 且未遵守第 10 条规定义务时， 授权代表应与制造商一样为缺陷器械承担法律责任， 并一样负有共同连带责任。 Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

6. 根据第 3 段（h）点所述的理由终止任务的授权代表应立即将任务的终止和原因通知其所在成员国的主管机构，适当时也可通知参与该器械符合性评估的公告机构。 An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

7. 本法规中对制造商注册营业地的成员国主管机构的任何引用应理解为， 根据第 1 段指定在制造商有注册经营地的授权代表的成员国内， 对主管机构的参考地址。 Any reference in this Regulation to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by a manufacturer referred to in paragraph 1, has its registered place of business.

第 12 条 Article 12

授权代表变更 Change of authorised representative

授权代表变更的详细安排应在制造商间的协议中明确规定， 本协议应对即将卸任与新任的授权代表可行。 本协议应至少解决以下几个方面： The detailed arrangements for a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable the outgoing authorised representative, and the incoming authorised representative. That agreement shall address at least the following aspects:

(a) 即将卸任的授权代表，其授权的终止日期为新任授权代表的授权开始日期； the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative;

(b) 直至授权代表将卸任的日期可在由制造商提供的，包括任何宣传材料的信息上注明； the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) 文件传输，包括机密性方面和产权； the transfer of documents, including confidentiality aspects and property rights;

(d) 授权结束后，将即将卸任授权代表的义务转交给制造商或新任授权代表，来自医护专业人员、患者和使用者，与由授权代表指定器械相关可疑事件的投诉和举报。 the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative.

第 13 条 Article 13

进口商的一般义务 General obligations of importers

1. 仅当器械遵照本法规时，进口商才能将器械投入欧盟市场。 Importers shall place on the Union market only devices that are in conformity with this Regulation.

2. 为将器械投放市场，进口商应核实以下事项： In order to place a device on the market, importers shall verify that:

(a) 该器械已作 CE 标识，且欧盟器械符合性声明已起草完毕； the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) 制造商已确定，按照第 11 条，授权代表由制造商来指定； a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;

(c) 该器械按照本法规和要求的使用说明进行标记； the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;

(d) 即，如适用，按照第 27 条， UDI 由制造商指定。 where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.

如进口商认为或有理由相信器械不符合本法规的要求，在器械符合要求前不得将其投放市场，并应通知制造商及其授权代表。如进口商认为或有理由相信该器械出现严重的风险，或为伪造器械，其还应通知进口商所在成员国的主管机构。 Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.

3. 进口商应在器械上或其包装上或随附文件上注明其名称、注册商号或注册商标，及其经营注册地和可联系到进口商的地址，以便确定其位置。它们应确保任何附加标签，不会掩盖制造商提供标签上的任何信息。 Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

4. 进口商应核实该器械有按照第 29 条于电子系统注册。 进口商应按照第 31 条，将其详细资料添加注册。 Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.

5. 进口商应确保器械在其责任、储存或运输条件下，不损害其遵守附录 I 所列的通用安全与性能要求，且如适用应遵守制造商所列条件。 Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.

6. 进口商应保存不合格器械和召回及撤回投诉记录，并提供制造商、授权代表和经销商以其所要求的所有信息，以便于其进行研究投诉。 Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints

7. 如进口商认为或有理由相信其投放到市场上的器械不符合本法规，应立即通知制造商及制造商授权代表。进口商应与制造商、制造商授权代表及主管机构合作，确保已采取必要的纠正措施，如使器械符合要求，撤回器械或召回器械。当器械出现严重风险，其也应立即通知各成员国主管机构哪些器械可用，如适用，公告机构应按照第 56 条颁发证书，至于有问题的器械，给出细节，特别是未遵守要求及其采取的纠正措施。 Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent

authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.

8. 如进口商收到来自医护专业人员、患者和使用者，关于投放于市场器械的相关可疑事件的投诉和举报，应立即通知制造商及其授权代表。 Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.

9. 进口商应在第 10（8）条所指期间，保留欧盟符合性声明副本，如适用，保留根据第 56 条发出的，包括所有校正和补充的相关证书副本。 Importers shall, for the period referred to in Article 10(8), keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.

10. 进口商应与主管机构合作，按后者要求，采取任何行动以消除或，如不可行，减轻其投放于市场器械导致的风险。进口商按成员国主管机构要求，若进口商有其经营注册地，应提供免费器械样品或，如不可行，允许访问该器械。 Importers shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

第 14 条 Article 14

经销商的一般义务 General obligations of distributors

1. 在器械上市时， 经销商应在其活动范围内， 适当谨慎地执行适用的要求。 When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. 在器械可于市场购得前，经销商应核实是否满足以下要求： Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) 该器械已作 CE 标识，且器械欧盟符合性声明已起草完毕； the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) 该器械与制造商按照第 10（11）条提供的信息相符； the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);

(c) 关于进口器械，进口商已遵守第 13（3）条列出的要求； for imported devices, the importer has complied with the requirements set out in Article 13(3);

(d) 如适用，制造商已指定 UDI 。 that, where applicable, a UDI has been assigned by the manufacturer.

为满足第一子段（ a)、（b）和（ d）点所述要求，经销商可申请由抽样获得的代表性器械。 In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

如经销商认为或有理由相信器械不符合本法规的要求，在器械符合要求前不可将器械推向市场，同时应通知制造商及（如适用）制造商授权代表与进口商。如经销商认为或有理由相信该器械出现严重的风险，或为伪造器械，他还应通知其所在成员国的主管机构。 Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised

representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

3. 经销商应确保器械在其责任范围内时，储存或运输条件应符合制造商规定。Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

4. 如经销商认为或有理由相信，投放市场的器械不符合本法规，应立即通知制造商和（如适用）制造商授权代表和进口商。经销商应与制造商、主管机构和（如适用）制造商授权代表与进口商合作，以确保已采取必要的纠正措施，以使器械符合要求、撤回器械或召回器械。如经销商认为或有理由相信该器械出现严重风险，其也应立即通知器械销售所在成员国的主管机构，给出细节，特别是未遵守要求及其采取的纠正措施。

Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

5. 如经销商收到来自医护专业人员、患者和使用者，关于可购得器械相关可疑事件的投诉和举报，应立即将此信息通知制造商和（如适用）制造商授权代表和进口商。其应保存不合格器械和撤回投诉记录，并通知制造商和（如适用）授权代表及经销商此种监控，并按其要求向其提供所有信息。

Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

6. 应主管机构请求，经销商应自主提供足以证明器械法规符合性的所有资料和文件。当制造商或授权代表（如适用）针对上述器械提供所需信息时，应视为经销商已履行第一子段中所述的该义务。经销商应主管机构要求，配合主管机构，采取任何行动以消除其在市场上所提供器械带来的风险。经销商应主管机构要求提供免费的器械样品，或者若无法提供免费样品，则应授予对器械的访问权。

Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

第 15 条 Article 15

负责法规符合性的人员职责 Person responsible for regulatory compliance

1. 制造商应在其组织内至少拥有一名在医疗器械领域具有必要专业知识的人员负责法规符合性。必要的专业知识应表现为以下任一一种资格：

Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) 在完成有关成员国确认为同等学历的法律、医学、药学、工程或其他相关科学学科大学学历或学习课程后颁发的文凭、证书或其他正式资格证书，以及在体外诊断医疗器械相关法规事务或质量管理体系方面具有至少一年专业经验； a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) 在法规事务或与医疗器械有关的质量管理体系方面有四年的专业经验。

four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

(c) 在不影响关于国家专业资格的规定的情况下，定制器械的制造商可凭借其在相关制造领域至少两年的专业经验证明第一子段所述的所需专门知识。

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

2. 在委员会第 2003/361/EC 号建议（[1]）含义范围内的微型和小型企业在其组织内无需有负责法规符合性的人员，但应有可永久且持续听其调遣的该类人员。

Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC (36) shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

([1]) 2003 年 5 月 6 日关于定义微型和中小型企业的委员会第 2003/361/EC号建议。

3. 负责法规符合性的人员至少应负责确保以下事项：

The person responsible for regulatory compliance shall at least be responsible for ensuring that:

(a) 根据制造这些器械的质量管理体系，在器械发布前适当检查器械法规符合性；

the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

(b) 制定技术文件和欧盟符合性声明并保持其最新状态；

the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;

(c) 遵守第 10（10）)条规定的上市后监管义务；

the post-market surveillance obligations are complied with in accordance with Article 10(10);

(d) 履行第 87 至 91 条中规定的报告义务；

the reporting obligations referred to in Articles 87 to 91 are fulfilled;

（e） 若为试验用器械，则发出附录 XV 第 XV 章第 4.1 节所述的声明。

in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued.

4. 若根据第 1、2 和第 3 段规定，多人共同负责法规符合性，则其各自的责任领域应以书面形式规定。

If a number of persons are jointly responsible for regulatory compliance in accordance with paragraphs 1, 2 and 3, their respective areas of responsibility shall be stipulated in writing.

5. 在制造商组织内负责法规符合性的人员，不论其是否属于该组织的雇员，在履行其职责方面不得有任何不利。 The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

6. 授权代表应至少有一名可永久且持续听其调遣的负责法规符合性的人员，其在欧盟境内的医疗器械监管要求方面拥有必要的专业知识。必要的专业知识应表现为以下任一一种资格：

Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

（a） 在完成有关成员国确认为同等学历的法律、医学、药学、工程或其他相关科学学科大学学历或学习课程后颁发的文凭、证书或其他正式资格证书，以及在体外医疗器械相关法规事务或质量管理体系方面具有至少一年专业经验； a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

（b） 在法规事务或与医疗器械有关的质量管理体系方面有四年的专业经验。 four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

第 16 条 Article 16

制造商的义务适用于进口商、经销商或其他人的情况

Cases in which obligations of manufacturers apply to importers, distributors or other persons

1. 经销商、 进口商或其他自然人或法人若做出以下任何行为， 则应承担制造商相应义务： A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) 在市场上提供以其名字、注册商标名称或注册商标命名的器械，除非经销商或进口商与标签上标明的制造商签订协议，仅由制造商承担本法规对制造商规定的要求； makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) 变更已投放市场或投入使用的器械的预期用途； changes the intended purpose of a device already placed on the market or put into service;

(c) 更改已投放市场或投入使用的器械，且对符合性产生影响。 modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be

affected.

第一子段不适用于为个别患者组装或改装已上市器械（且未更改器械之预期用途）的任何人员（此等人员并不视为第 2 条第（ 30）点所定义之制造商） 。 The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in point (30) of Article 2, assembles or adapts for an individual patient a device already on the market without changing its intended purpose.

2. 对于第 1 段（ c）点而言，以下情况不得视为器械更改可能影响其适用要求的合规情况： For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) 提供附录 I 第 23 节规定已投放市场器械的制造商信息，以及用于在相关成员国推销器械所需的进一步信息，包括此等信息的译文； provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) 对已投放市场器械的外包装改变，若为在相关成员国推销该器械而必需重新包装，且若重新包装不会影响器械原始状态，包括改变包装尺寸，则可进行。对于无菌器械，应保证无菌状态的原始包装，因为重新包装将对必要用于维护无菌状态的包装、损害将会对无菌状态产生不良影响。 changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. 任何进行第 2 段（ a）及（ b）点活动的经销商或进口商应在器械上或者（如不可行）在其包装上或者器械所附的文件上对其所进行的活动标明其名称、注册商标名或者注册商标、业务注册地及有效联系地址及设立位置。

经销商和进口商应确保具有一套质量管理体系，其中的流程应保证信息译文准确及时更新，还应保证在保持器械原始状态不变的方式和条件进行第 2 段（ a）和（ b）点中的活动以及保证重新包装的器械包装应无缺陷，质量良好且整洁。质量管理体系除此之外还应包括这些程序：确保经销商或进口商充分了解任何有关安全问题或合规问题的纠正行动。 A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. The quality management system shall cover, inter alia, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. 至少在对上市器械重贴标签或重新包装 28 天前，进行第 2 段第（ a）和（ b）点中所述活动的经销商或进口商，应通知在中所述的拟提供重贴标签或重新包装器械的制造商和所在成员国主管机构，并根据要求应向制造商和主管机构提供一个重贴标签或重新包装器械的样品或实体模型，包括任何翻译版本的标签和说明书。在该 28 天内的同一时期内，其应当向主管机构提交一份证书，该证书由公告机构颁发给用于进行第 2 段（ a）和（ b）点所述活动器械，用于证明该经销商或进口商质量管理体系符合在第 3 段中规定的要求。 At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out

any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

第 17 条 Article 17

一次性使用器械及其再处理

Single-use devices and their reprocessing

1. 一次性使用器械的再处理和进一步使用只能在国家法律允许的情况下进行，且只能按照本文进行 .

Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.

2. 任何对一次性使用器械进行再处理以使其适合在欧盟内进一步使用的自然人或法人应视为再处理器械的制造商，并承担本法规所规定的制造商义务， 包括根据本法规第 III 章，与再处理器械可追溯性有关的义务。对于第 85/374/EEC 号指令第 3(1)条的目的，器械再处理者应视为生产者。

Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.

3. 通过对第 2 段的豁免，对于在卫生机构中再处理和使用的一次性使用器械，成员国可决议不采用与本法规中规定的制造商义务有关的所有规则，但前提是其确保

By way of derogation from paragraph 2, as regards single-use devices that are reprocessed and used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in this Regulation provided that they ensure that: ：

(a) 再处理器械的安全性和性能与原器械的安全性和性能相同， 且遵循第 5（5）条（a)、（b)、(d)、(e)、(f)、(g）和（ h）点中的要求； the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements in points (a), (b), (d), (e), (f), (g) and (h) of Article 5(5) are complied with;

(b) 根据 CS 执行再处理，其中详细说明以下方面的要求： the reprocessing is performed in accordance with CS detailing the requirements concerning:

- 关于风险管理，包括对器械的结构和材料，相关属性的分析（逆向工程）和检测原器械以及再处理后计划应用的设计变更程序， risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing,
- 关于验证整个过程程序，包括清洁步骤， the validation of procedures for the entire process, including cleaning steps,
- 关于产品的上市和性能测试， the product release and performance testing,
- 关于质量管理体系， the quality management system,

- 关于涉及已进行再处理的器械事件报告, the reporting of incidents involving devices that have been reprocessed, and
- 关于再处理器械的可追溯性。 the traceability of reprocessed devices.

成员国应鼓励并要求卫生机构向患者提供关于在卫生机构内使用再处理器械的信息，并酌情提供患者治疗采用的再处理器械的任何其他相关信息。 Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

成员国应将根据本段提出的国家规定和提出这些规定的理由通知委员会和其他成员国。委员会应将信息公开。

Member States shall notify the Commission and the other Member States of the national provisions introduced pursuant to this paragraph and the grounds for introducing them. The Commission shall keep the information publicly available.

4. 成员国可选择采用第 3 段所述的规定，也适用于应卫生机构的要求由外部再处理者再处理的一次性使用器械，但前提是将再处理器械全部返回该卫生机构，并且外部再处理者遵循第 3 段第（ a）和（ b）点中所述的要求。

Member States may choose to apply the provisions referred to in paragraph 3 also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the requirements referred to in points (a) and (b) of paragraph 3.

5. 委员会应根据第 9(1) 条，自 2020 年 5 月 26 日起采用第 3 段第（ b）点中所述的必要 CS。这些 CS 应符合最新科学证据， 并应适用于本法规所规定的关于安全与性能的一般要求。 若自 2020 年 5 月 26 日起未采用 CS，则应根据任何包括在第 3 段第（b）点中所列方面相关协调标准和国家规定进行再处理。 符合通用规范， 或在无通用规范的情况下，相关协调标准和国家规定应由公告机构进行认证。

The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be certified by a notified body.

6. 根据第 93/42/EEC 号指令，仅有按照本法规或在 2020 年 5 月 26 日之前投放市场的一次性使用器械可进行再处理。Only single-use devices that have been placed on the market in accordance with this Regulation, or prior to 26 May 2020 in accordance with Directive 93/42/EEC, may be reprocessed.

7. 只能对根据最新科学证据视为安全的一次性使用器械进行再处理。 Only reprocessing of single-use devices that is considered safe according to the latest scientific evidence may be carried out.

8. 第 2 段中所述的法人或自然人的姓名和地址以及附录 I 第 23 节中规定的其他相关信息， 应在标签上标明， 并在适用的情况下在再处理器械的使用说明中注明。 The name and address of the legal or natural person referred to in paragraph 2 and the other relevant information referred to in Section 23 of Annex I shall be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

一次性使用器械原制造商的名称和地址不再出现在标签上，但应在再处理器械的使用说明书中所述。

The name and address of the manufacturer of the original single-use device shall no longer appear on the label, but shall be mentioned in the instructions for use of the reprocessed device.

9. 允许一次性使用器械再处理的成员国可维持或实行比本法规规定及限制或禁止更严格的国家规定，并在其领土内限制或禁止实施以下行为： A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:

(a) 一次性使用器械的再处理以及为进行再处理而将一次性使用器械转移至另一成员国或第三国； the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;

(b) 再处理的一次性使用器械的提供或进一步使用。 the making available or further use of reprocessed single-use devices.

成员国应将国家规定通知委员会和其他成员国。委员会应将该信息公开。

Member States shall notify the Commission and the other Member States of those national provisions. The Commission shall make such information publicly available.

11. 委员会应在 2024 年 5 月 27 日起草关于本条实施情况的报告，并将其提交欧洲议会和理事会。根据本报告，委员会应酌情提出修订修订本法规的建议。

The Commission shall by 27 May 2024 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. On the basis of that report, the Commission shall, if appropriate, make proposals for amendments to this Regulation.

第 18 条 Article 18

将提供给患者的植入器械植入物卡和信息

Implant card and information to be supplied to the patient with an implanted device

1. 可植入器械的制造商应连同该器械一起提供以下内容： The manufacturer of an implantable device shall provide together with the device the following

(a) 器械标识信息，包括器械名称、序列号、批号、UDI 、器械型号，以及制造商名称、地址和网站； information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) 患者或医疗保健专业人员对可合理预见的外部影响、医学检查或环境条件的相互干扰采取的任何警戒、预防措施或举措； any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(c) 关于器械的使用期限的任何信息和任何必要的跟踪； any information about the expected lifetime of the device and any necessary follow-up;

(d) 任何其他确保患者安全使用该器械的信息，包括附录 I 第 23.4 节第（u）点的信息。 any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

出于提供给特殊患者目的，在第一子段总所述的信息应通过任何方式提供给已植入器械的特定患者，使其可快速获取信息，并以相关成员国确定的语言表述。信息的表达方式应使非专业人士容易理解并应酌情更新，且应通过第 1 段（a）点所述的网站向患者提供更新信息。 The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph

此外，制造商应在与器械一起交付的植入物卡片上提供第一子段（ a）点规定的信息。

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device

2. 成员国应要求卫生机构过允许患者快速获取信息，并向已进行器械植入且具有其身份的植入物卡的患者提供第 1 段中所述的信息。

Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identity.

3. 以下植入物应免除本文规定的职责：缝合线、 U 形钉、牙齿填料、牙弓、牙冠、螺钉、楔子、板线、针、夹子和连接器。 委员会有权根据第 115 条采用授权方案， 通过增加其他类植入物或从中删除植入物来修订这一清单。

The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

第 19 条 Article 19

欧盟符合性声明 EU declaration of conformity

1. 欧盟符合性声明须说明已履行本法规中相关涵盖器械规定的要求。制造商应当不断更新欧盟符合性声明。欧盟符合性声明至少应包括列于附录 IV 的信息，且应将其翻译成欧盟官方语言或者器械销售所在成员国所要求的语言。 The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

2. 就本法规未涵盖的相关问题，若器械需遵守其他欧盟立法机构要求（该立法机构要求制造商发布一份证实已履行该立法机构所规定要求的欧盟符合性声明） ，只需要起草有关所有欧盟法案均适用该器械的单独符合性声明。这一声明应包含所有标识声明书相关欧盟立法机构的必要信息。 Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

3. 通过起草欧盟符合性声明，制造商应承担遵守本法规和适用于器械的所有其他欧盟立法机构要求的责任。 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.

4. 委员会应有权按照第 115 条规定通过授权法案， 基于技术进步来修订附录 IV 规定的欧盟符合性声明的最低限度内容。 The Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the EU declaration of conformity set out in Annex IV in the light of technical progress.

第 20 条 Article 20

CE 符合性标识 CE marking of conformity

1. 除了定制或研究用器械外， 视为符合本法规要求的器械应加贴如附录 V 中所示的合规 CE 标识。 Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V.

2. CE 标识应遵守列于欧洲委员会第 765/2008 号法规第 30 条要求的一般原则。 The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. 标签应明显、清晰和不可磨灭地添加在器械或其无菌包装上。考虑到器械性质，无法或不适合将标签添加到器械上时， 应将 CE 标识添加在包装上。 CE 标识也应加贴在有使用说明和任何销售包装中。 The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

4. 应在器械上市前加贴 CE 标识。其可能紧跟在任一个表示特殊危险或用途的象形图或任何其他标记后面。 The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

5. 如适用， CE 标识应紧跟在负责进行列于第 52 条的符合性评估流程的公告机构标识号后面。且应在任何宣传材料（其中所述器械满足 CE 标识的要求） 中说明标识号。 Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

6. 若器械需遵守欧盟立法机构要求添加 CE 标识的其他规定，则 CE 标识还应表明该器械符合其他立法机构要求。 Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

第 21 条 Article21

用于特殊用途的器械 Devices for special purpose

1. 成员国不得造成任何障碍： Member States shall not create obstacles to:

(a) 提供给研究员用于临床研究的试验用器械，前提是在根据第 81 条和附录 XV 规定执行采用的法案时，符合第 62 条至第 80 条和 82 条所规定的条件； investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the conditions laid down in Articles 62 to 80 and Article 82, in the implementing acts adopted pursuant to Article 81 and in Annex XV;

(b) 可在市场上提供的定制器械，前提是符合第 52（8）条和附录 XIII 的规定。 custom-made devices being made available on the market if Article 52(8) and Annex XIII have been complied with

在第一子段中所述的器械（在第 74 条中所述的器械除外）不得加贴 CE 标识。 The devices referred to in the first subparagraph shall not bear the CE marking, with the exception of the devices referred to in Article 74.

2. 定制器械应附有附录 XIII 第 1 节所述的声明，该声明应提供给以名称、首字母缩略词或数字代码标识的特定患者或使用者。 Custom-made devices shall be accompanied by the statement referred to in Section 1 of Annex XIII, which shall be made available to the particular patient or user identified by name, an acronym or a numerical code.

成员国可要求定制器械的制造商向主管机构提交在其领土内可获得的此类器械的清单。 Member States may require that the manufacturer of a custom-made device submit to the competent authority a list of such devices which have been made available in their territory

3. 在交易会、展览会、展示会或类似活动上，成员国不得制造任何障碍，表明器械不符合本法规要求，但前提是在器械上清楚标明一个明显记号表明该器械仅用于展示或演示目的且在未符合本法规之前不可投入使用。 At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create obstacles to the showing of devices which do not comply with this Regulation, provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with this Regulation.

第 22 条 Article 22

系统和手术包 Systems and procedure packs

1. 任何自然人或法人若根据器械或其他产品的预期用途并在制造商指定的使用限制范围内，将带有 CE 标识的器

械与下列其他器械或产品一起组合，则应起草第 2 段所述的声明，以将它们作为系统或手术包投放市场： Natural or legal persons shall draw up a statement if they combine devices bearing a CE marking with the following other devices or products, in a manner that is compatible with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:

(a) 其他带 CE 标识的器械； other devices bearing the CE marking;

(b) 带有符合欧盟第 2017/746 号法规的 CE 标识的体外诊断医疗器械； in vitro diagnostic medical devices bearing the CE marking in conformity with Regulation (EU) 2017/746;

(c) 仅在其在医疗程序中使用或证明其在系统或手术包中另外存在时，才符合适用于这些产品的立法的其他产品。 other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

2. 在第 1 段中所做的说明中，自然人或法人应声明如下： In the statement made pursuant to paragraph 1, the natural or legal person concerned shall declare that:

(a) 其已根据制造商的说明验证了器械和其他产品（如适用）间的相互兼容性，并根据这些说明执行了其活动； they verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and have carried out their activities in accordance with those instructions;

(b) 其将系统或手术包打包并向使用者提供相关信息，其中整合了器械或其他同一包装内产品制造商应当供应的信息； they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;

(c) 将器械和其他产品（如适用）作为系统或手术包进行组合的活动需要采用适当的内部监测、验证和确认方法。 the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

3. 对第 1 段所述的系统或手术包进行消毒并将其投放市场的任何自然人或法人，应在其选择下遵循附录 IX 或附录 XI 的 A 部分所述的程序之一。这些程序的应用和公告机构的参与应限于确保灭菌直至无菌包装打开或损坏的程序层面。该自然人或法人应起草一份声明书，声明已按照制造商的说明进行灭菌。 Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at their choice, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. The application of those procedures and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged. The natural or legal person shall draw up a statement declaring that sterilisation has been carried out in accordance with the manufacturer's instructions.

4. 若系统或手术包包含不带 CE 标识的器械，或所选择的器械组合由于其原始预期用途而不兼容，或未根据制造商的说明进行消毒，则系统或手术包应视为独立的器械，并应依照第 52 条进行相关的符合性评估流程。此外，自然人或法人应承担制造商的义务。 Where the system or procedure pack incorporates devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, or where the sterilisation has not been carried out in accordance with the manufacturer's instructions, the system or procedure pack shall be treated as a device in its own right and shall be subject to the relevant conformity assessment procedure pursuant to Article 52. The natural or legal person shall assume the obligations incumbent on manufacturers.

5. 本条第 1 段所述的系统或手术包本身不得带附加 CE 标识，但应带有本条第 1 段和第 3 段所述人员的姓名、注

册商标名称或注册商标以及可与其联系并确定该人员位置的地址。 系统或手术包应附有附录 I 第 23 节所述的资料。在将系统或手术包组合后，在适用于根据第 10（8）条组合的器械的期间，将本条第 2 段所述的声明交由主管机构保管处置。若这些期间不同，则应采用最长的期间。 The systems or procedure packs referred to in paragraph 1 of this Article shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraphs 1 and 3 of this Article as well as the address at which that person can be contacted, so that the person's location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 23 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable under Article 10(8) to the devices that have been combined. Where those periods differ, the longest period shall apply.

第 23 条 Article 23

部件和组件 Parts and components

1. 任何在市场上提供专门用于取代相同或类似的有缺陷或磨损器械组成部分或组件的物品，以维持或恢复器械功能的自然人或法人，应在不改变器械性能或安全特征或其预期用途情况下，保证该物品对器械安全与性能没有不利影响。支持性证据应可供成员国主管机构随时获取。 Any natural or legal person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

2. 专门用于替代器械部件或组件和显著改变器械性能或安全特征或预期用途的物品，应视为器械且应满足本法规规定的要求。 An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation.

第 24 条 Article 24

自由流通 Free movement

除非本法规另有规定， 否则成员国不得拒绝、 禁止或限制在其领土内提供或使用符合本法规要求的器械。 Except where otherwise provided for in this Regulation, Member States shall not refuse, prohibit or restrict the making available on the market or putting into service within their territory of devices which comply with the requirements of this Regulation.

第 III 章 CHAPTER III

器械的标识和可追溯性、器械和经济运营商的登记、安全和临床性能总结、欧洲医疗器械数据库 IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

第 25 条 Article 25

供应链中标识 Identification within the supply chain

1. 经销商和进口商应与制造商或授权代表合作， 以实现器械适当水平的可追溯性。 Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of

devices.

2. 在第 10（8）条所述期限，经济运营商应能够向主管机构确定以下内容： Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8):

(a) 其直接提供器械的任何经济运营商； any economic operator to whom they have directly supplied a device;

(b) 直接向其提供器械的任何经济运营商； any economic operator who has directly supplied them with a device;

(c) 其直接提供器械的任何卫生机构或卫生保健专业人员。 any health institution or healthcare professional to which they have directly supplied a device.

第 26 条 Article 26

医疗器械的命名 Medical devices nomenclature

为协助根据第 33 条设立的欧洲医疗器械数据库 “ Eudamed ”的运作， 委员会应确保国际公认的医疗器械命名应就本法规而言， 免费提供给需要使用命名的制造商和其他自然人或法人。委员会还应努力确保在合理可行的情况下免费向其他利益相关方提供这一命名。 To facilitate the functioning of the European database on medical devices (‘ Eudamed ’) referred to in Article 33, the Commission shall ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

第 27 条 Article 27

唯一器械标识系统 Unique Device Identification system

1. 附录 VI 第 C 部分中说明的唯一器械标识系统（ ‘ UDI 系统’）应允许标识除定制和研究器械以外的器械并促进该器械的可追溯性， 此外还应包括以下内容： The Unique Device Identification system (‘ UDI system ’) described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of the following:

(a) UDI 的包括以下几点： production of a UDI that comprises the following:

(i) 特定于某一制造商和器械的 UDI 器械标识符（ ‘ UDI-DI ’），提供附录 VI 第 B 部分所述信息访问途径； a UDI device identifier (‘ UDI-DI ’) specific to a manufacturer and a device, providing access to the information laid down in Part B of Annex VI;

(ii) UDI 生产标识符 （‘ UDI-PI ’），用于标识所生产的器械单元以及附录 VI 第 C 部分中规定的包装后器械（若适用）；a UDI production identifier (‘ UDI-PI ’) that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

(b) 将 UDI 应用于器械的标签或其包装上； placing of the UDI on the label of the device or on its packaging;

(c) 经济运营商、卫生机构和卫生专业人员根据本条第 8 和 9 段规定的条件储存 UDI ；storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9 of this Article respectively;

(d) 根据第 28 条为唯一器械标识建立 UDI 电子系统 （“ UDI 数据库 ”）。establishment of an electronic system for Unique Device Identification (‘ UDI database ’) in accordance with Article 28.

2. 委员会应通过实施细则指定一个或多个实体来根据本法规规定操作一个 UDI 分配系统（委任实体） 。实体应满足以下所有标准： The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation (‘ issuing entity ’). That entity or those entities shall satisfy all of the following criteria:

(a) 实体是具有法人资格的组织； the entity is an organisation with legal personality;

(b) 其 UDI 分配系统足以根据本法规要求，在从分销到使用的整个过程中标识器械； its system for the assignment of UDIs is adequate to identify a device throughout its distribution and use in accordance with the requirements of this Regulation;

(c) 其 UDI 分配系统符合相关国际标准； its system for the assignment of UDIs conforms to the relevant international standards;

(d) 该实体可根据一组预定的和透明的条款和条件，将 UDI 分配系统的访问权限提供给所有相关使用者； the entity gives access to its system for the assignment of UDIs to all interested users in accordance with a set of predetermined and transparent terms and conditions;

(e) 该实体做出以下几点承诺： the entity undertakes to do the following;

(i) 在得到委任后，应能够运作其 UDI 分配系统至少 10 年； operate its system for the assignment of UDIs for at least 10 years after its designation;

(ii) 提供给委员会和各成员国使用，并应要求，提供 UDI 分配系统的相关信息； make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;

(iii) 保持遵守指定标准和指定条款。 remain in compliance with the criteria for designation and the terms of designation.

委任签发实体时，委员会应努力确保无论委任的实体使用何种系统，如附录 VI 第 C 部分所定义的 UDI 载体均能够通过通用方式可读，并可为经济运营商和卫生机构减少财务和行政负担。 When designating issuing entities, the Commission shall endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators and health institutions.

3. 在将器械（除了定制器械外）投放于市场前，制造商应向该器械和（如适用）所有更大的包装分配一个符合委员会根据第 2 段委任的签发实体颁布规则所产生的 UDI 。Before placing a device, other than a custom-made device, on the market, the manufacturer shall assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of the issuing entity designated by the Commission in accordance with paragraph 2.

Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer shall ensure that the information referred to in Part B of Annex VI of the device in question are correctly submitted and transferred to the UDI database referred to in Article 28

4. UDI 载体应添加在该器械标签和所有更大包装上。较大的包装不包括海运集装箱。 UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers.

5. 根据第 87 条，UDI 应用于报告严重事件和现场安全纠正措施。 The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.

6. 第 19 条所述的欧盟符合性声明应载明该器械的基本 UDI-DI （定义见附录 VI 第 C 部分）。The Basic UDI-DI, as defined in Part C of Annex VI, of the device shall appear on the EU declaration of conformity referred to in Article 19.

7. 制造商应及时更新所有应用 UDI 的清单作为附录 II 中所述技术文件的一部分。 As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

8. 经济运营商最好应以电子方式存储和保存其所供应或所接受的器械 UDI，若这些器械属于： Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with

which they have been supplied, if those devices belong to:

- III 类植入式器械； class III implantable devices;
- 由第 11 段（ a）点中所指措施确定的器械、类别或器械组。 the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 11.

9. 若这些器械属于 III 类植入式器械， 则医疗机构应优先以电子方式存储和保持其所供应或接受的器械 UDI 。Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices.

除了 III 类植入式器械外，成员国应鼓励并可要求医疗机构优先以电子方式储存和保管接受的器械 UDI 。 For devices other than class III implantable devices, Member States shall encourage, and may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

成员国应鼓励，并可要求健康护理人员优先通过电子手段存放和保管提供给其器械的 UDI 。Member States shall encourage, and may require, healthcare professionals to store and keep preferably by electronic means, the UDI of the devices with which they have been supplied with.

10. 委员会应有权根据第 115 条通过以下授权法案： The Commission is empowered to adopt delegated acts in accordance with Article 115:

(a) 从技术进步的角度修订或补充载列于附录 VI 第 B 部分的资料清单； 及 amending the list of information set out in Part B of Annex VI in the light of technical progress; and

(b) 就唯一器械标识领域的国际发展及技术进步修订或补充附录 VI 。 amending Annex VI in the light of international developments and technical progress in the field of Unique Device Identification.

11. 委员会可通过实施细则规定模式及程序，以确保以下任何几个方面的唯一器械标识系统的协调适用： The Commission may, by means of implementing acts, specify the detailed arrangements and the procedural aspects for the UDI system with a view to ensuring its harmonised application in relation to any of the following:

(a) 采用第 8 段规定的义务确定器械、类别或器械组别。 determining the devices, categories or groups of devices to which the obligation laid down in paragraph 8 is to apply;

(b) 规定包括在器械或器械组别的 UDI -PI 的数据；specifying the data to be included in the UDI-PI of specific devices or device groups;

应按照第 114(3)条中述及的审查规程通过这些在第一子段中所述的实施细则。 The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

12. 采用第 11 段所述措施时，委员会应考虑以下事项： When adopting the measures referred to in paragraph 11, the Commission shall take into account all of the following:

（a） 第 109 和 8110 条中所述的保密性和数据保护； confidentiality and data protection as referred to in Articles 109 and 110 respectively;

（b） 基于风险的方法； the risk-based approach;

（c） 措施的成本收益； the cost-effectiveness of the measures;

（d） 以国际水准开发 UDI 系统； the convergence of UDI systems developed at international level;

（e） 避免 UDI 系统重复的需要； the need to avoid duplications in the UDI system;

（f） 成员国对医疗卫生系统的需要，及在尽可能的情况下，与利益相关方使用的其他医疗器械的识别系统的兼容性。 the needs of the healthcare systems of the Member States, and where possible, compatibility with other medical device identification systems that are used by stakeholders.

第 28 条 Article 28

UDI 数据库 UDI database

1. 委员会应与 MDCG 商议后设立和管理一个 UDI 数据库，以验证、整理、处理附录 VI 第 B 部分所述信息，并向公众公布此等信息。 The Commission, after consulting the MDCG shall set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Annex VI.

2. 设计 UDI 数据库时， 委员会应考虑在附录 VI 第 C 部分第 5 节说明的 UDI 数据库的一般原则。 UDI 数据库设计应特别满足无 UDI-PI 且其中无商业机密产品信息。 When designing the UDI database, the Commission shall take into account the general principles set out in Section 5 of Part C of Annex VI. The UDI database shall be designed in particular such that no UDI-PIs and no commercially confidential product information can be included therein.

3. 附录 VI 第 B 部分中所述的 UDI 数据库核心数据元素应免费向公众开放。 The core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public free of charge.

4. 电子系统的技术设计应保证存储在 UDI 数据库信息的最大可用性， 并允许多个使用者访问和自动上传和下载信息。委员会应对 UDI 数据库的制造商和其他使用者提供技术和管理支持。 The technical design of the UDI database shall ensure maximum accessibility to information stored therein, including multi-user access and automatic uploads and downloads of that information. The Commission shall provide for technical and administrative support to manufacturers and other users of the UDI database.

第 29 条 Article 29

器械注册 Registration of devices

1. 在市场上投放一个非定制器械时，制造商应遵守第 27（2）条所述的发行实体的规则，向器械分配附录 VI 第 C 部分定义的基本 UDI －DI 并将其与附录 VI 第 B 部分中所述的相关器械的其他核心数据要素提交给 UDI 数据库。

2. 根据第 22(1)和（3）条，在市场投放一个非定制器械的系统或手术包，责任自然人或法人应按照指定发行实体的规则，向系统或手术包分配基本 UDI －DI，并将其与在附录 VI 第 B 部分中定义的相关系统或手术包的其他核心数据要素一并提交至 UDI 数据库。 Before placing a device, other than a custom-made device, on the market, the manufacturer shall, in accordance with the rules of the issuing entity referred to in Article 27(2), assign a Basic UDI-DI as defined in Part C of Annex VI to the device and shall provide it to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

3. 对于经过第 52（3）条或第 52（4）条第二和第三子段中符合性评估的器械，在器械投放市场前，制造商应在公告机构运用符合性评估流程前向器械分配基本的 UDI －DI 前向器械分配一个本条第 1 段中所述的 UDI-DI 。 For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in the second and third subparagraphs of Article 52(4), the assignment of a Basic UDI-DI referred to in paragraph 1 of this Article shall be done before the manufacturer applies to a notified body for that assessment.

对于在第一子段中所述的器械，公告机构应按照附录 XII 第一章第 4 节 a 点包括出具证书上基本 UDI-DI 的参考并确认附录 VI 第 A 部分第 2.2 节中所述的 Eudamed。在出具相关证书及在将器械投放在市场之前，制造商应将基本的 UDI-DI 及附录 VI 第 B 部分中定义的相关系统或手术包的其他核心数据要素。 For the devices referred to in the first subparagraph, the notified body shall include a reference to the Basic UDI-DI on the certificate issued in accordance with point (a) of Section 4 of Chapter I of Annex XII and confirm in Eudamed that the information referred to in Section 2.2 of Part A of Annex VI is correct. After the issuing of the relevant certificate and before placing the device on the market, the manufacturer shall provide the Basic UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

5. 将非定制器械投放在市场之前，制造商应提交或者若已提交，验证附录 VI 第 A 部分第 2 节（第 2..2 节除外）中所述的 Eudamed 资料并应及时更新。 Before placing a device on the market, other than a custom-made device, the

manufacturer shall enter or if, already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and shall thereafter keep the information updated.

第 30 条 Article 30

经济营运商注册电子系统 Electronic system for registration of economic operators

1. 在咨询 MDCG 后，委员会应建立并管理电子系统以创建第 31（2）条所述的单一注册号整理及加工识别制造商及（如适用）授权代表及进口商的必要且相应的资料。有关经济营运商提供至电子系统的资料详情载于附录 VI 第 A 部分第 1 节。The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article 31(2) and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be provided to that electronic system by the economic operators are laid down in Section 1 of Part A of Annex VI.

2. 成员国可维持或引用有关其领土范围内允许使用的器械的经销商注册的国家规定。 Member States may maintain or introduce national provisions on registration of distributors of devices which have been made available on their territory.

3. 非定制器械投放市场两周内，进口商应核实制造商或授权代表已将第 1 段中所述的资料提交至电子系统中。Within two weeks of placing a device, other than a custom-made device, on the market, importers shall verify that the manufacturer or authorised representative has provided to the electronic system the information referred to in paragraph 1.

若第 1 段中所述的资料未上传或不正确，在适用的情况下，进口商应通知相关授权代表或制造商。进口商应将其详细资料添加到相关条目。 Where applicable, importers shall inform the relevant authorised representative or manufacturer if the information referred to in paragraph 1 is not included or is incorrect. Importers shall add their details to the relevant entry/entries.

第 31 条 Article 31

制造商、授权代表和进口商的注册

Registration of manufacturers, authorised representatives and importers

1. 在非定制器械投放市场前，制造商、授权代表和进口商为实现注册，应当向第 30 条中所述的电子系统提交附录 VI 第 A 部分第 1 节所述的资料。前提是其并未根据本条进行注册。若根据第 52 条符合性评估流程需要公告机构参与，应在向公告机构申请前向电子系统提交附录 VI 第 A 部分第 1 节所述的资料。 Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI, provided that they have not already registered in accordance with this Article.
In cases where the conformity assessment procedure requires the involvement of a notified body pursuant to Article 52, the information referred to in Section 1 of Part A of Annex VI shall be provided to that electronic system before applying to the notified body.

2. 在核实根据第 1 段输入的数据后，主管机构应自第 30 条所述的电子系统取得单一注册号（'SRN'）并签发给制造商、授权代表或进口商。 After having verified the data entered pursuant to paragraph 1, the competent authority shall obtain a single registration number ('SRN') from the electronic system referred to in Article 30 and issue it to the manufacturer, the authorised representative or the importer.

3. 制造商向公告机构申请进行符合性评估和评估 Eudamed（为履行第 29 条项下的义务）时需要用到单一注册号。 The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 29.

4. 如有关本条第 1 段所述的资料于一周内发生任何变动，相关经济营运商应当更新第 30 条中所述电子系统中的数据。 Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 30.

5. 提交第 1 段所述的资料后不迟于一年及此后的每两年，相关经济营运商应确认数据的准确性。在六个月到期日内未确认的情况下，任何成员国可于其领土范围内采取适当的纠正措施，直至本段所述义务得到履行。 Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation.

6. 在不影响经济营运商对数据的责任的情况下，主管机构应核实附录 VI 第 A 部分第 1 节中所述的已确认的数据。 Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in Section 1 of Part A of Annex VI.

7. 根据本条第 1 段录入第 30 条所述的电子系统中的数据应向公众开放。 The data entered pursuant to paragraph 1 of this Article in the electronic system referred to in Article 30 shall be accessible to the public.

8. 根据第 111 条，主管机构可利用这些数据对制造商、授权代表或进口商收费。 The competent authority may use the data to charge the manufacturer, the authorised representative or the importer a fee pursuant to Article 111.

第 32 条 Article 32

安全和临床性能总结 Summary of safety and clinical performance

1. 对于 III 类器械和植入式器械（非定制或研究器械），制造商应起草一份安全和临床性能总结。 For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

该安全和临床性能总结应令拟定使用者及（如相关）患者明白，并应通过 Eudamed 向公众开放。 The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed

本安全和临床性能总结的草案应当是提交予依照第 52 条所参与符合性评估的公告机构文件的一部分，并由该机构来验证。验证后，公告机构应将该总结报告上传到 Eudamed。制造商应在标签或使用说明所述总结报告可获得的地址。 The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available.

2. 安全和临床性能总结应至少包括以下方面： The summary of safety and clinical performance shall include at least the following aspects:

(a) 器械和制造商标识，包括基本 UDI - DI 和 SRN（如已发布）；the identification of the device and the manufacturer, including the Basic UDI-DI and, if already issued, the SRN;

(b) 该器械的预期用途，包括任何适应症、禁忌症和目标人群； the intended purpose of the device and any indications, contraindications and target populations

(c) 该器械的说明，包括前一代或变体（如存在）的参考文件，和差别说明，以及附件、其他器械和其他产品等与该器械联合使用的产品说明； ; a description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device;

(d) 可能的诊断或治疗替代品； possible diagnostic or therapeutic alternatives;

(e) 协调标准和 CS 的参考文件； reference to any harmonised standards and CS applied;

(f) 附录 XIV 中参考的临床评价总结和上市后临床跟踪的相关信息； the summary of clinical evaluation as referred to in Annex XIV, and relevant information on post-market clinical follow-up;

(g) 为使用者提供的建议简况和培训； suggested profile and training for users;

(h) 有关任何剩余风险和任何不良影响、警戒和预防措施的信息。 information on any residual risks and any undesirable effects, warnings and precautions.

3. 委员会可通过实施细则，载列将纳入安全和临床性能总结的数据元素的形式及声明。应按照第 114(2) 条中述及的咨询规程通过这些实施细则。 The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and clinical performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

第 33 条 Article 33

欧洲医疗器械数据库

European database on medical devices

1. 委员会应出于下列目的，与 MDCG 商议后，设立、维护和管理欧洲医疗器械数据库（'Eudamed'）：The Commission, after consulting the MDCG, shall set up, maintain and manage the European database on medical devices ('Eudamed') for the following purposes:

(a) 帮助公众对投放于市场的器械、认证机构发出的相应证书及相关经济运营商有充分的了解； to enable the public to be adequately informed about devices placed on the market, the corresponding certificates issued by notified bodies and about the relevant economic operators;

(b) 实现内部市场上器械的唯一标识，并促进可追溯性； to enable unique identification of devices within the internal market and to facilitate their traceability;

(c) 帮助公众充分了解临床研究情况，并要求临床研究申办方遵守第 62 至 80 条和 82 条以及任何根据第 81 条所采用的法案规定的义务； to enable the public to be adequately informed about clinical investigations and to enable sponsors of clinical investigations to comply with obligations under Articles 62 to 80, Article 82, and any acts adopted pursuant to Article 81;

(d) 要求制造商遵守第 87 至 90 条或任何根据第 91 条所采用法案规定的信息义务； to enable manufacturers to comply with the information obligations laid down in Articles 87 to 90 or in any acts adopted pursuant to Article 91;

(e) 使成员国和委员会的主管机构能够在充分知情的基础上执行与本法规有关的任务，并加强它们间的合作。 to enable the competent authorities of the Member States and the Commission to carry out their tasks relating to this Regulation on a well-informed basis and to enhance the cooperation between them.

2. Eudamed 应包括以下电子系统： Eudamed shall include the following electronic systems:

(a) 在第 29（4）条中所述器械注册电子系统； the electronic system for registration of devices referred to in Article 29(4);

(b) 第 28 条所指的 UDI 数据库； the UDI-database referred to in Article 28;

(c) 在第 30 条中所述的经济运营商电子登记系统； the electronic system on registration of economic operators referred to in Article 30;

(d) 在第 57 条中所述的认证机构和证书电子系统； the electronic system on notified bodies and on certificates referred to in Article 57;

(e) 在第 73 条中所述的临床研究电子系统； the electronic system on clinical investigations referred to in Article 73;

(f) 第 92 条所指的警戒和上市后监管电子系统； the electronic system on vigilance and post-market

surveillance referred to in Article 92;

(g) 第 100 条所指的市场监管电子系统。 the electronic system on market surveillance referred to in Article 100.

3. 设计 Eudamed 时，委员会应充分考虑国家数据库和国家网络接口的兼容性以允许数据的输入和输出。 When designing Eudamed the Commission shall give due consideration to compatibility with national databases and national web-interfaces to allow for import and export of data.

4. 应由成员国、认证机构、经济运营商和申办方，根据第 2 段中所述电子系统的规定，将数据录入 Eudamed。委员会应向 Eudamed 使用者提供技术和行政支持。 The data shall be entered into Eudamed by the Member States, notified bodies, economic operators and sponsors as specified in the provisions on the electronic systems referred to in paragraph 2. The Commission shall provide for technical and administrative support to users of Eudamed.

5. Eudamed 整理并加工所有信息，应可供成员国和委员会访问。第 2 段所述有关电子系统规定中定义的范围内，向认证机构、经济运营商、申办方和公众应可访问该信息。 All the information collated and processed by Eudamed shall be accessible to the Member States and to the Commission. The information shall be accessible to notified bodies, economic operators, sponsors and the public to the extent specified in the provisions on the electronic systems referred to in paragraph 2

委员会应确保 Eudamed 公共部分以使用者友好且易于搜索的形式呈现。

6. Eudamed 所包含的个人数据，应当方便本条第 2 段中所述电子系统根据本法规规定进行整理和处理。个人数据的保存形式应能够使数据主体标识时间不长于第 10（8）条所述期限。 Eudamed shall contain personal data only insofar as necessary for the electronic systems referred to in paragraph 2 of this Article to collate and process information in accordance with this Regulation. Personal data shall be kept in a form which permits identification of data subjects for periods no longer than those referred to in Article 10(8).

7. 委员会和成员国应当确保数据主体可分别按照欧洲委员会第 45/2001 号法规和第 95/46/EC 号指令，有效行使其知情权以及获取、纠正和反对的权利。其应确保数据主体能够有效地行使与其有关的数据访问权，并有权纠正或删除不准确或不完整的数据。在各自的职责范围内，委员会和各成员国应确保按照适用的法律删除不准确的和非法处理的数据。应尽快进行更正和删除，但不得迟于数据主体提出请求后 60 天。 The Commission and the Member States shall ensure that data subjects may effectively exercise their rights to information, of access, to rectification and to object in accordance with Regulation (EC) No 45/2001 and Directive 95/46/EC, respectively. They shall also ensure that data subjects may effectively exercise the right of access to data relating to them, and the right to have inaccurate or incomplete data corrected and erased. Within their respective responsibilities, the Commission and the Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable legislation. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days after a request is made by a data subject.

8. 委员会应通过实施细则，以制定设立和维护 Eudamed 所必需的形式。应按照第 114（3）条中述及的审查规程通过这些实施细则。当采纳这些实施细则时，委员会应尽可能确保系统的开发能够在同一模块或系统的不同模块内-输入同一资料两次。 The Commission shall, by means of implementing acts, lay down the detailed arrangements necessary for the setting up and maintenance of Eudamed. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). When adopting those implementing acts, the Commission shall ensure that, as far as possible, the system is developed in such a way as to avoid having to enter the same information twice within the same module or in different modules of the system.

9. 关于其在本条下的责任和其中所涉及个人数据的处理，应将委员会视为 Eudamed 及其电子系统的控制者。 In relation to its responsibilities under this Article and the processing of personal data involved therein, the

Commission shall be considered to be the controller of Eudamed and its electronic systems

第 34 条 Article 34

Eudamed 的功能

Functionality of Eudamed

1. 委员会应与 MDCG 协作，为 Eudamed 制定功能规范。委员会应最迟于 2018 年 5 月 26 日制定实施这些规范的计划。这一计划将寻求确保 Eudamed 在规定日期完全运转，即该日期允许委员会于 2020 年 3 月 25 日公布第 3 段中所述通知，且本法规第 123 条和第 2017/746 号法规第 113 条的所有其他相关最后期限都得到满足。 The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018. That plan shall seek to ensure that Eudamed is fully functional at a date that allows the Commission to publish the notice referred to in paragraph 3 of this Article by 25 March 2020 and that all other relevant deadlines laid down in Article 123 of this Regulation and in Article 113 of Regulation (EU) 2017/746 are met.

2. 一旦在 UDI 上确认 Eudamed 已实现全部功能，且 Eudamed 符合根据第 1 段制定的职能规范，委员会应通过独立审计报告来通知 MDCG 。 The Commission shall, on the basis of an independent audit report, inform the MDCG when it has verified that Eudamed has achieved full functionality and Eudamed meets the functional specifications drawn up pursuant to paragraph 1.

3. 委员会应在咨询 MDCG 后，在确认第 2 段中所述条件已得到满足时，在欧盟公报上公布相应通知。 The Commission shall, after consultation with the MDCG and when it is satisfied that the conditions referred to in paragraph 2 have been fulfilled, publish a notice to that effect in the Official Journal of the European Union.

第 IV 章 CHAPTER IV

公告机构

NOTIFIED BODIES

第 35 条 Article 35

负责公告机构的主管机构

Authorities responsible for notified bodies

1. 任何成员国如指定符合性评估机构作为公告机构，或已指定一家公告机构根据本法规开展符合性评估活动，则应根据国家法律任命一个由单独实体组成的主管机构 （负责公告机构的主管机构） ，负责建立和开展评估、 指定符合性评估机构和符合性评估公告的必要流程，以及公告机构（包括其分包商和分支机构）的监管。 Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority (‘ authority responsible for notified bodies ’), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

2. 负责公告机构的主管机构应当妥善建立、组织和运作，以保障其活动的客观性和公正性，并避免与符合性评估

机构的任何利益冲突。 The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.

3. 负责公告机构的主管机构应当妥善组织，使指定或公告相关的每个决议均由未参与评估的人员做出。 The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.

4. 负责公告机构的主管机构不得参与由公告机构组织的商业或竞争性活动。 The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

5. 负责公告机构的主管机构应当保护其获得信息的保密性。但是，可与其他成员国、委员会及其他法规机构（在需要时）交换有关公告机构的信息。 The authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on notified bodies with other Member States, the Commission and, when required, with other regulatory authorities.

6. 负责公告机构的主管机构应拥有足够数量的永久供其履行任务的合资格人员。 The authority responsible for notified bodies shall have a sufficient number of competent personnel permanently available for the proper performance of its tasks.

在负责公告机构的主管机构与负责医疗器械的主管机构是另一家时，应确向负责医疗器械的国家主管机构就相关问题展开咨询。 Where the authority responsible for notified bodies is a different authority from the national competent authority for medical devices, it shall ensure that the national authority responsible for medical devices is consulted on relevant matters.

7. 成员国可公开获得一般资料，包括对符合性评估机构的评估、指定、公告和对公告机构监管的规定，以及对这些任务有重大影响的变化。 Member States shall make publicly available general information on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

8. 负责公告机构的主管机构应参与第 48 条规定的同行审查活动。 The authority responsible for notified bodies shall participate in the peer-review activities provided for in Article 48.

第 36 条 Article 36

公告机构的相关要求

Requirements relating to notified bodies

1. 公告机构应根据本法规实现指定给其任务，且应满足组织和总体要求以及必需的质量管理、资源和流程要求，以使其具备履行本法规指定任务的资格。 尤其是， 该公告机构须符合附录 VII 的要求。 Notified bodies shall fulfil the tasks for which they are designated in accordance with this Regulation. They shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil those tasks. In particular, notified bodies shall comply with Annex VII.

为满足这些在第一子段中所述的要求， 公告机构应按照附录 VII 第 3.1.1 节可永久获得充足的行政、 技术和科研人员，按照附录 VII 第 3.2.4 条永久获得相关临床专业人员，如有可能，可由公告机构自行聘用。 n order to meet the requirements referred to in the first subparagraph, notified bodies shall have permanent availability of sufficient administrative, technical and scientific personnel in accordance with Section 3.1.1 of Annex VII and personnel with relevant clinical expertise in accordance with Section 3.2.4 of Annex VII, where possible employed by the notified body itself.

附录 VII 第 3.2.3 及 3.2.7 条所述的人员应由公告机构自行聘用， 聘用人员不得为外部专家或分包商。 The personnel referred to in Sections 3.2.3 and 3.2.7 of Annex VII shall be employed by the notified body itself and shall not be external experts or subcontractors.

2. 公告机构应按要求编制并提交所有可获得的相关文件（包括制造商文件）至负责公告机构的主管机构，使其能够开展评估、 指定、公告、监督及监管活动， 以促进本章节内所述的评估。 Notified bodies shall make available and submit upon request all relevant documentation, including the manufacturer's documentation, to the authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined in this Chapter.

3. 为确保附录 VII 要求的统一应用，委员会应按照第 114(3)条中所述的检查程序采取实施细则，并在必要情况下解决分歧和实际应用中的问题。 In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt implementing acts, to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 37 条 Article 37

分支机构和分包 Subsidiaries and subcontracting

1. 若公告机构将与符合性评估相关的特定任务分包， 或分派给分支机构， 则应确认分包商或分支机构符合附录 VII 中规定的适用要求，并通知负责公告机构的主管机构。 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VII and shall inform the authority responsible for notified bodies accordingly

2. 公告机构应对分包商或分支机构代表其履行任务承担全部责任。 Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.

3. 公告机构应公开其分支机构名单。 Notified bodies shall make publicly available a list of their subsidiaries.

4. 在告知申请符合性评估的法人或自然人后，符合性评估活动可转包或由分支机构开展。 Conformity assessment activities may be subcontracted or carried out by a subsidiary provided that the legal or natural person that applied for conformity assessment has been informed accordingly.

5. 公告机构应保证负责公告机构的主管机构拥有关于分包商或分支机构资格鉴定及其根据本法规开展工作的所有

相关文件的处置权。 Notified bodies shall keep at the disposal of the authority responsible for notified bodies all relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

第 38 条 Article 38

符合性评估机构的提交的委任申请

Application by conformity assessment bodies for designation

1. 符合性评估机构应向负责公告机构的主管机构提交委任申请。

Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies.

2. 申请应明确本法规中规定的符合性评估活动，以及申请委任的器械类型，并有附录 VII 中证明符合性文件的支持。

The application shall specify the conformity assessment activities as defined in this Regulation, and the types of devices for which the body is applying to be designated, and shall be supported by documentation demonstrating compliance with Annex VII.

关于附录 VII 第 1 节和第 2 节所规定的组织和一般要求以及质量管理要求，国家委任机构根据欧盟第 765/2008 号法规提交的有效认证证书和相应的评估报告， 并在第 39 条所述的评估中予以考虑。 但申请机构应准备第一子段提及的所有文件以证明符合这些要求。

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 39. However, the applicant shall make available all the documentation referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

3. 为确保负责公告机构的主管机构对是否符合附录 VII 的所有要求进行持续监督和确认，如有任何相关变化，公告机构应更新第 2 段中所述的文件。

The notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

第 39 条 Article 39

申请评估 Assessment of the application

1. 负责公告机构的主管机构应在 30 天内检查第 38 条所述的申请是否完成，并要求申请机构提供缺失信息。一旦申请完成， 主管机构应将其交送委员会。 The authority responsible for notified bodies shall within 30 days check that the application referred to in Article 38 is complete and shall request the applicant to provide any missing information. Once the application is complete that authority shall send it to the Commission.

负责公告机构的主管机构应按照自己的程序审查申请和支持文件，并起草一份初步评估报告。 The authority responsible for notified bodies shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.

2. 负责公告机构的主管机构应向委员会提交初步评估报告，委员会应立即将报告转交至 MDCG 。 The authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the MDCG.

3. 在本条第 2 段所述的递交后 14 天内，委员会和 MDCG 从第 40（2）条的名单中选出三个专家组成联合评估小组，如遇特殊情况可改变专家人数。其中一位专家应为委员会的代表，负责协调联合评估小组的活动。另外两

个专家应分别来自不同于申请机构符合性评估的两个成员国。 Within 14 days of the submission referred to in paragraph 2 of this Article, the Commission, in conjunction with the MDCG, shall appoint a joint assessment team made up of three experts, unless the specific circumstances require a different number of experts, chosen from the list referred to in Article 40(2). One of the experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team. The other two experts shall come from Member States other than the one in which the applicant conformity assessment body is established.

联合评估小组应由合格的专家组成，能评定符合性评估活动和该申请中的器械类型，特别是在根据第 47（3）条启动该评估流程后，确保特定关注点可得到正确评估。 The joint assessment team shall be comprised of experts who are competent to assess the conformity assessment activities and the types of devices which are the subject of the application or, in particular when the assessment procedure is initiated in accordance with Article 47(3), to ensure that the specific concern can be appropriately assessed.

4. 联合评估小组应在委任后的 90 天内，审核根据第 38 条提交的申请文件。联合评估小组可向负责公告机构的主管机构提供关于申请和计划现场评估的反馈，或要求其澄清。 Within 90 days of its appointment, the joint assessment team shall review the documentation submitted with the application in accordance with Article 38. The joint assessment team may provide feedback to, or require clarification from, the authority responsible for notified bodies on the application and on the planned on-site assessment

负责公告机构的主管机构以及联合评估小组，应计划并实施对符合性评估申请机构以及欧盟内外参与符合性评估过程的分支机构或分包商进行现场评估。 The authority responsible for notified bodies together with the joint assessment team shall plan and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or subcontractor, located inside or outside the Union, to be involved in the conformity assessment process.

申请机构的现场评估应由负责公告机构的主管机构领导。 The on-site assessment of the applicant body shall be led by the authority responsible for notified bodies.

5. 如发现申请符合性评估机构的申请人不符合附录 VII 要求时，应在评估过程中提出，并经负责公告机构的主管机构和联合评估小组讨论，以对该申请的评估达成共识和消除分歧。 Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VII shall be raised during the assessment process and discussed between the authority responsible for notified bodies and the joint assessment team with a view to reaching consensus and resolving any diverging opinions, with respect to the assessment of the application.

在现场评估结束时，负责公告机构的主管机构将向申请符合性评估机构提供因联合评估小组提供的评估和评价总结产生的不符合项清单。 At the end of the on-site assessment, the authority responsible for notified bodies shall list for the applicant conformity assessment body the non-compliances resulting from the assessment and summarise the assessment by the joint assessment team.

在规定的时间内，符合性评估机构申请人应向国家主管机构提交纠正和预防措施计划，以解决不符合项。 Within a specified timeframe, the applicant conformity assessment body shall submit to the national authority a corrective and preventive action plan to address the non-compliances.

6. 联合评估小组应在完成现场评估后的 30 天内记录有关评估的剩余分歧意见，并将这些意见提交给负责公告机构的主管机构。 The joint assessment team shall document any remaining diverging opinions with respect to the assessment within 30 days of completion of the on-site assessment and send them to the authority responsible for notified bodies.

7. 负责公告机构的主管机构应当在收到申请机构提供的纠正和预防措施计划后，判断评估过程中发现的不符合项是否已经合理解决。该计划应说明所识别不符合项问题的根本原因并应包括执行操作的时间表。 The authority

responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall indicate the root cause of the identified non-compliances and shall include a timeframe for implementation of the actions therein.

负责认证机构的主管机构在确认纠正和预防措施计划后， 应将该计划及其对该计划的意见转交给联合评估小组。可要求负责认证机构的主管机构的联合评估小组进一步澄清和修改。 The authority responsible for notified bodies shall having confirmed the corrective and preventive action plan forward it and its opinion thereon to the joint assessment team. The joint assessment team may request of the authority responsible for notified bodies further clarification and modifications.

负责公告机构的主管机构应拟定其最终的评估报告，包括： The authority responsible for notified bodies shall draw up its final assessment report which shall include:

- 评估结果， the result of the assessment,
- 确认已采取纠正和预防措施，并在需要时实施 confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,
- 与联合评估小组的剩余分歧意见， 和（如适用） ny remaining diverging opinion with the joint assessment team, and, where applicable,
- 建议的委任范围。 the recommended scope of designation.

8. 负责公告机构的主管机构应向委员会、 MDCG 和联合评估小组提交最终评估报告和委任草案（如适用） 。The authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.

9. 联合评估小组应在收到由负责公告机构的主管机构准备的评估报告和委任草案（如适用）后 21 天内，向委员会提供关于这些文件的最终意见，且委员会应立即将此最终意见提交给 MDCG 。在收到联合评估小组意见后 42 天内， MDCG 应就委任草案提出建议，负责公告机构的主管机构应在其做出委任公告机构的决议时充分考虑该建议。 The joint assessment team shall provide a final opinion regarding the assessment report prepared by the authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit that final opinion to the MDCG. Within 42 days of receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation, which the authority responsible for notified bodies shall duly take into consideration for its decision on the designation of the notified body.

10. 委员会可通过实施细则，采取措施设定第 38 条规定的申请委任和本条规定的申请评估的流程和报告的详细协议。按照第 114(3)条的审查流程采用这些实施细则。 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements specifying procedures and reports for the application for designation referred to in Article 38 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 40 条 Article 40

公告申请联合评估专家的提名

Nomination of experts for joint assessment of applications for notification

1. 成员国和委员会应提名医疗器械领域内具备符合性评估机构评估资格的专家参与第 39 条和第 48 条所述的活动。

The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of medical devices to participate in the activities referred to in Articles 39 and 48.

2. 委员会应根据本条第 1 段生成一个提名专家名单, 及其具体能力和专业信息领域。 该名单应当通过第 57 条的电子系统向成员国主管机构公布。 The Commission shall maintain a list of the experts nominated pursuant to paragraph 1 of this Article, together with information on their specific field of competence and expertise. That list shall be made available to Member States competent authorities through the electronic system referred to in Article 57.

第 41 条 Article 41

语言要求 Language requirements

第 38 条和第 39 条要求的所有文件应以一种或多种相关成员国的语言拟定。 All documents required pursuant to Articles 38 and 39 shall be drawn up in a language or languages which shall be determined by the Member State concerned.

成员国在采用第一子段时应考虑在全部或部分有关文件中使用医学领域通用易懂的语言。 Member States, in applying the first paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documentation concerned.

委员会应对第 38 和 39 条提供的文件进行必要翻译，或将部分翻译为欧盟官方语言，使按照第 39(3)条指派的联合评估小组能够理解文档内容。 The Commission shall provide translations of the documentation pursuant to Articles 38 and 39, or parts thereof into an official Union language, such as is necessary for that documentation to be readily understood by the joint assessment team appointed in accordance with Article 39(3).

第 42 条 Article 42

委任和公告流程 Designation and notification procedure

1. 成员国只能指定已完成第 39 条评估并符合附录 VII 所列要求的符合性评估机构。 Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 39 was completed and which comply with Annex VII.

2. 成员国应使用公告机构数据库内委员会开发和管理的电子公告工具（ NANDO ），将其委任的符合性评估机构通知委员会和其他成员国。 Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).

3. 该公告应利用本条第 13 段中所述的法规明确规定本法规所定义的符合性评估活动的委任范围、 授权公告机构评估的器械类型以及不影响第 44 条的与委任相关的条件。 The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the types of devices which the notified body is authorised to assess and, without prejudice to Article 44, any conditions associated with the designation.

4. 公告应附有负责公告机构的主管机构的最终评估报告、第 39（9）条所指联合评估小组的最终意见和 MDCG 的建议。若通知成员国未遵循 MDCG 的建议，应提供有充分证据的理由。 The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 39(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.

5. 在不影响第 44 条的情况下，公告成员国应向委员会和其他成员国通报与委任有关的任何情况，并提供关于现有安排的书面证据，以确保定期监督公告机构并将继续满足附录 VII 的要求。 The notifying Member State shall, without prejudice to Article 44, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.

6. 在第 2 段中所述的公告后 28 天内，成员国或委员会可书面提出异议，就关于公告机构或负责公告机构的主管机构对其进行的监督进行讨论。若未提出异议，委员会应在 42 天内在第 2 段所述的 NANDO 内发布公告。 Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.

7. 当成员国或委员会根据第 6 段提出异议时，委员会应在第 6 段所述的期限到期后 10 天内将该事项提交 MDCG 。经与有关各方协商， MDCG 应至少在其收到该事项后 40 天内给出其意见。若 MDCG 认为可接受该公告，则委员会应在 14 天在 NANDO 公布公告。When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.

8.. 若 MDCG 在根据第 7 段进行磋商后，确认现有异议或提出另一异议，公告成员国应在收到 MDCG 意见后 40 天内做出书面答复。其答复应处理意见中提出的异议，并说明公告成员国决议指定或不指定该符合性评估机构的原因。 Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.

9. 若公告成员国在根据第 8 段给出其说明理由后决议任命符合性评估机构，则委员会应在收到通知后 14 天内在 NANDO 中公布该公告。 Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.

10. 当在 NANDO 中发布公告时，委员会还应在第 57 条所述的电子系统中增加与该公告机构的通知相关的信息、 本条第 4 段中所述的文件以及该条第 7 和 8 段中所述的意见和答复。 When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article.

11. 该委任应在 NANDO. 发布该公告后生效。 公布通知应说明公告机构的合法活动范围。 The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

12. 有关的符合性评估机构只有在根据第 11 条委任生效后才能开展公告机构的活动。 The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11.

13. 委员会应在 2017 年 11 月 26 日，通过实施细则起草一份代码和对应的器械类型清单，以说明公告机构的委任范围。且应按照第 114(3)条中述及的审查流程通过这些实施细则。委员会在咨询 MDCG 后，更新本清单，除此之

外可更新根据第 48 条协调活动提供的信息。 The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission, after consulting the MDCG, may update this list based, inter alia, on information arising from the coordination activities described in Article 48.

第 43 条 Article 43

标识号和公告机构名单

Identification number and list of notified bodies

1. 委员会应根据第 42（11）条为各公告机构分配一个有效标识号。即使该机构已在欧盟多个活动中被任命，委员会也应为其指定一个唯一标识号。如根据本法规成功指定后，公告机构应根据第 90/385 和 93/42/EEC 号指令保留根据这些指令分配的标识号。 The Commission shall assign an identification number to each notified body for which the notification becomes valid in accordance with Article 42(11). It shall assign a single identification number even when the body is notified under several Union acts. If they are successfully designated in accordance with this Regulation, bodies notified pursuant to Directives 90/385/EEC and 93/42/EEC shall retain the identification number assigned to them pursuant to those Directives.

2. 委员会将基于本法规生成机构名单，包括分配的标识号、本法规定义的符合性评估活动以及公告的器械类型，这些在 NANDO 向公众公开。该清单还应在第 57 条所述的电子系统中公布。委员会应确保清单实时更新。 The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in NANDO. It shall also make this list available on the electronic system referred to in Article 57. The Commission shall ensure that the list is kept up to date.

第 44 条 Article 44

公告机构的监督和再评估 **Monitoring and re-assessment of notified bodies**

1. 公告机构应最迟在 15 天内，尽快向负责公告机构的主管机构通报可能影响其遵守附录 VII 要求或其进行指定器械相关的符合性评估活动的相关变化。 Notified bodies shall, without delay, and at the latest within 15 days, inform the authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VII or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.

2. 负责公告机构的主管机构应监督其境内的公告机构及其分支机构和分包商，以确保其持续符合本法规要求并履行其义务。此外，公告机构应根据负责公告机构的主管机构的要求，提供使主管机构、委员会和其他成员国能够验证所需的所有相关信息和文件符合性。 The authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. Notified bodies shall, upon request by their authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance.

3. 若委员会或成员国主管机构向另一成员国（相关由该机构开展的符合性评估）境内设立的公告机构，其应向负责另一成员国公告机构的主管机构发送一份副本将收到一个由委员会或另一成员国主管机构提交的副本，该副本列有对其境内公告机构执行有关符合性认证情况的所有要求。相关的公告机构在收到该要求后应立即回复，

最迟不超过 15 天。成员国负责公告机构的主管机构应确保任一其他成员国主管机构或委员会向其境内设立的公告机构提交的要求得到解决，如有合法理由拒绝，可提交 MDCG 处理。 Where the Commission or the authority of a Member State submits a request to a notified body established on the territory of another Member State relating to a conformity assessment carried out by that notified body, it shall send a copy of that request to the authority responsible for notified bodies of that other Member State. The notified body concerned shall respond without delay and within 15 days at the latest to the request. The authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved by the notified body unless there is a legitimate reason for not doing so in which case the matter may be referred to the MDCG.

4. 负责公告机构（无论其是否在其各自领域设立）的主管机构应至少每年一次，重新评审每家公告机构（且在合适时应包含其分支机构及由其负责的分包商）是否仍然符合要求，以及是否履行了附录 VII 列出的应尽义务。评审应包含对每一家公告机构（必要时，对其分支机构和分包商）的现场审核。 At least once a year, the authorities responsible for notified bodies shall re-assess whether the notified bodies established on their respective territory and, where appropriate, the subsidiaries and subcontractors under the responsibility of those notified bodies still satisfy the requirements and fulfil their obligations set out in Annex VII. That review shall include an on-site audit of each notified body and, where necessary, of its subsidiaries and subcontractors.

负责公告机构的主管机构应按照年度评估计划执行监管和评估活动以确保其能有效监督公告机构一直遵守本法规的要求。该计划应确定合理的时间表，特别应对公告机构及相关分支机构和分包商的评估频率做出规定。该主管机构应就其管辖的每家公告机构向 MDCG 和委员会提交年度监管或评估计划。 The authority responsible for notified bodies shall conduct its monitoring and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. That plan shall provide a reasoned schedule for the frequency of assessment of the notified body and, in particular, associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.

5. 负责公告机构的主管机构对公告机构的监管应包括对公告机构员工的证据审核，必要时可在制造商工厂内进行质量管理体系评估时，对分支机构和分包商的员工进行审核。 The monitoring of notified bodies by the authority responsible for notified bodies shall include observed audits of notified body personnel, including where necessary any personnel from subsidiaries and subcontractors, as that personnel is in the process of conducting quality management system assessments at a manufacturer's facility.

6. 负责公告机构的主管机构对公告机构执行的监管应考虑从市场监管、警戒和上市后监管所获得的数据，以帮助指导其活动。 The monitoring of notified bodies conducted by the authority responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance to help guide its activities.

负责公告机构的主管机构应提供一个跟踪体系来处理投诉和其他信息，来源包括其他成员国，这些投诉或信息可能显示公告机构没有履行应尽义务或偏离常规或最佳行为准则。 The authority responsible for notified bodies shall provide for a systematic follow-up of complaints and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

7. 负责公告机构的主管机构除了定期监督或现场评估外，如需解决特定问题或查证守法情况，还可采取临时通知、暗访或“有因”核查的行动。 The authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or ‘cause-for’ reviews if needed to address a particular issue or to verify compliance.

8. 负责公告机构的主管机构将评估公告机构对制造商技术，尤其是临床文档的评估，进一步规定参加第 45 条。 The authority responsible for notified bodies shall review the assessments by notified bodies of manufacturers' technical documentation, in particular the clinical evaluation documentation as further outlined in Article 45.

9. 负责公告机构的主管机构应记录并存档有关公告机构不符合附录 VII 要求的发现并监督其及时采取纠正和预防措施。 The authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VII and shall monitor the timely implementation of corrective and preventive actions.

10. 公告机构通告成立后三年以及此后每隔 4 年，成员国负责公告机构的主管机构应全面重新评估设立于该国境内的公告机构，以确定其是否仍符合附录 VII 的要求，并按照第 38 条和 39 条所述流程指定联合评审小组。 Three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VII shall be conducted by the authority responsible for notified bodies of the Member State in which the body is established and by a joint assessment team appointed for the purpose of the procedure described in Articles 38 and 39.

11. 委员会有权按照第 115 条采纳授权法案以修改第 10 段, 进而修订该段所述的已开展的全面重新评估的频率。 The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend paragraph 10 to modify the frequency at which the complete re-assessment referred to in that paragraph is to be carried out.

12. 成员国应当至少每年一次向委员会和 MDCG 报告对其境内公告机构及其分支机构和分包商 （如适用） 开展的监督行动和现场评估。 该报告应该详述这些活动的结果, 包括根据第 7 段进行的活动。 该报告应由 MDCG 和委员会视为机密信息，但其摘要可公开。 The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring and on-site assessment activities regarding notified bodies and, where applicable, subsidiaries and subcontractors. The report shall provide details of the outcome of those activities, including activities pursuant to paragraph 7, and shall be treated as confidential by the MDCG and the Commission; however it shall contain a summary which shall be made publicly available.

报告摘要应上传至第 57 条所述的电子系统。 The summary of the report shall be uploaded to the electronic system referred to in Article 57.

第 45 条 Article 45

对公告机构所评估的技术文件和性能评估报告的评审

Review of notified body assessment of technical documentation and clinical evaluation documentation

1. 作为对公告机构现行监管的一部分, 负责公告机构的主管机构应审查适当数量的由公告机构评估的制造商技术文件，尤其是附录 II 第 6.1 节（ c）点和（ d）点中所述的临床评价文件，以验证公告机构根据制造商提供的信息得出的结论。这些负责公告机构的主管机构进行的评估包括现场评估和现场外评估。 The authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies, shall review an appropriate number of notified body assessments of manufacturers' technical documentation, in particular the clinical evaluation documentation as referred to in points (c) and (d) of Section 6.1 of Annex II to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. The reviews by the authority responsible for notified bodies shall be conducted both off-site and on-site.

2. 按照第 1 段进行的文件抽查应按计划进行, 并能代表公告机构出具证书器械的类别和风险, 尤其是高风险器械, 在抽样计划中应有适当的理由和记录，以便在 MDCG 要求时负责公告机构的主管机构可获得这部分信息。 The sampling of files to be reviewed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body, in particular high-risk devices, and be appropriately justified and documented in a sampling plan, which shall be made available by the authority responsible for notified bodies to the MDCG upon request.

3. 负责公告机构的主管机构应审查公告机构所做的评估是否适当, 并检查所使用的流程、 相关文档和公告机构得出的结论。 该检查包括公告机构作为评估依据的制造商技术和临床评估文件。 并应利用 CS 进行这些审查。 The

authority responsible for notified bodies shall review whether the assessment by the notified body was conducted appropriately and shall check the procedures used, associated documentation and the conclusions drawn by the notified body. Such checking shall include the technical documentation and clinical evaluation documentation of the manufacturer upon which the notified body has based its assessment. Such reviews shall be conducted utilising CS.

4. 这些审查也是公告机构根据第 44（10）条进行重新评估和根据第 47（3）条进行联合评估活动的部分内容。进行这些审查需使用相应的专业知识。 Those reviews shall also form part of the re-assessment of notified bodies in accordance with Article 44(10) and the joint assessment activities referred to in Article 47(3). The reviews shall be conducted utilising appropriate expertise.

5. MDCG 可根据负责公告机构的主管机构或联合评估小组的审查和评估报告，第 VII 章中所述市场监管、警戒和上市后监管活动获取的信息，对技术进步的连续监测、对公众担忧和器械安全与性能的新问题的识别，建议按照本条规定进行抽样， 抽取的样本应包括更大或更小比例的由公告机构评估的技术文件和临床评估文件。 Based on the reports of the reviews and assessments by the authority responsible for notified bodies or joint assessment teams, on input from the market surveillance, vigilance and post-market surveillance activities described in Chapter VII, on the continuous monitoring of technical progress, or on the identification of concerns and emerging issues concerning the safety and performance of devices, the MDCG may recommend that the sampling, carried out under this Article, cover a greater or lesser proportion of the technical documentation and clinical evaluation documentation assessed by a notified body.

6. 委员会可通过实施细则，采取措施制订本条款所述的技术和临床评估文件模式、相关文档和协调要求。应按照第 114(3)条述及的审查流程通过这些实施细则。 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements, associated documents for, and coordination of, the review of assessments of technical documentation and clinical evaluation documentation, as referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 46 条 Article 46

委任与公告变更

Changes to designations and notifications

1. 负责公告机构的主管机构应通知委员会和其他成员国有关公告机构委任的任何后续相关变更。 The authority responsible for notified bodies shall notify the Commission and the other Member States of any relevant changes to the designation of a notified body.

第 39 条和第 42 条中所述流程适用于委任范围扩大的变更。 The procedures described in Article 39 and in Article 42 shall apply to extensions of the scope of the designation.

在非委任范围扩大的所有其他情况下，在以下段落中规定的程序应适用。 For changes to the designation other than extensions of its scope, the procedures laid down in the following paragraphs shall apply.

2. 委员会应立即在 NANDO 在公布修订后的公告。委员会应立即在电子系统输入第 57 条中所述的公告机构委任变化信息。 The Commission shall immediately publish the amended notification in NANDO. The Commission shall immediately enter information on the changes to the designation of the notified body in the electronic system referred to in Article 57.

3. 若公告机构决议停止其符合性评估活动，应尽快告知负责公告机构的主管机构和相关制造商，并且在停止评估活动前一年拟定停止计划。若另一公告机构书面确认为证书所包括的器械承担责任，其证书在停止公告机构活动后九个月内暂时有效。新的公告机构应在上述期限结束前完成对受影响器械的全面评估，方可为给这些器械

签发新的证书。 若公告机构停止其活动， 负责公告机构的主管机构应撤销该委任 Where a notified body decides to cease its conformity assessment activities it shall inform the authority responsible for notified bodies and the manufacturers concerned as soon as possible and in the case of a planned cessation one year before ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of the notified body's activities on condition that another notified body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates. The new notified body shall complete a full assessment of the devices affected by the end of that period before issuing new certificates for those devices. Where the notified body has ceased its activity, the authority responsible for notified bodies shall withdraw the designation.

4. 若负责公告机构的主管机构已确定公告机构不再符合附录 VII 的要求，或其未能履行自身义务，或未执行必要的纠正措施，主管机构可根据未达要求或不履行义务的严重程度，暂停、限制、全部或部分撤销对该机构的委任。一次暂停不得超过一年，但可追加一次同样期限的暂停。 Where a authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VII, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period.

负责公告机构的主管机构应将任何暂停、限制或撤销委任的情况立即通知委员会和其他成员国。 The authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a designation

5. 若委任已暂停、限制或全部或部分撤销，公告机构应在最迟 10 天内告知相关制造商。 Where its designation has been suspended, restricted, or fully or partially withdrawn, the notified body shall inform the manufacturers concerned at the latest within 10 days.

6. 若发生限制、暂停或撤销委任的情况，负责公告机构的主管机构应当采取适当步骤以确保公告机构的文件送达其他成员国负责公告机构的主管机构及其要求的负责市场监管的主管机构。 In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall take appropriate steps to ensure that the files of the notified body concerned are kept and make them available to authorities in other Member States responsible for notified bodies and to authorities responsible for market surveillance at their request.

7. 在限制、暂停或撤销委任的情况下，负责公告机构的主管机构应该： In the event of restriction, suspension or withdrawal of a designation, the authority responsible for notified bodies shall:

(a) 评估对公告机构所签发证书的影响； assess the impact on the certificates issued by the notified body;

(b) 在发出委任变更通知后 3 个月内向委员会和其他成员国报告结果； submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c) 要求公告机构在主管机构决议的合理期限内暂停或撤销任何不当签发的证书，以确保市场上的器械安全； require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued to ensure the safety of devices on the market;

(d) 将其要求暂停或撤销的所有证书录入第 57 条中所述的电子系统。 enter into the electronic system referred to in Article 57 information in relation to certificates of which it has required their suspension or withdrawal;

(e) 将其要求暂停或撤销的证书通过第 57 条所述的电子系统通知制造商或其授权代表经营注册地所在成员国的医疗器械主管机构。该主管机构应采取适当措施，以在必要时避免给患者、使用者或其他人的健康或安全带来潜在风险。 inform the competent authority for medical devices of the Member State in which the manufacturer has its registered place of business through the electronic system referred to in Article 57 of the certificates for which it has required suspension or withdrawal. That competent

authority shall take the appropriate measures, where necessary to avoid a potential risk to the health or safety of patients, users or others.

8. 除不当签发的证书外，在委任出现暂停或限制时，证书在以下情况下仍然有效： With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in the following circumstances:

(a) 负责公告机构的主管机构确认在暂停或限制的一个月内，相关证书的安全问题不受暂停或限制的影响；和负责公告机构的主管机构已制定了纠正暂停或限制的时间表和措施；或 the authority responsible for notified bodies has confirmed, within one month of the suspension or restriction, that there is no safety issue in relation to certificates affected by the suspension or restriction, and the authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction; or

(b) 负责公告机构的主管机构已确认在暂停或限制期间将不再签发、修订或重新签发与暂停相关的证书，并指出在暂停或限制期间公告机构是否有能力继续监管并负责现有的已签发证书。若负责公告机构的主管机构认为公告机构无能力支持现有已签发证书，则制造商应在暂停或限制 3 个月内向证书覆盖的器械制造商（有其自己的商业注册地）所在成员国主管机构书面确认由其他合格公告机构临时承担公告机构的监督职能，并继续负责暂停或限制期间的证书。 the authority responsible for notified bodies has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In the event that the authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide, to the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business, within three months of the suspension or restriction, a written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. 除不当签发的证书外，在撤销委任时，在以下情况下证书仍有 9 个月的有效期： With the exception of certificates unduly issued, and where a designation has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:

（a） 证书覆盖的器械制造商（有其自己商业注册地）所在成员国的医疗器械主管机构已确认未发生与上述器械相关的安全问题。 where the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its registered place of business has confirmed that there is no safety issue associated with the devices in question; and

（b） 其他公告机构书面确认将承担这些器械的直接责任，并在委任撤销起 12 个月内完成对器械的评估。 another notified body has confirmed in writing that it will assume immediate responsibilities for those devices and will have completed assessment of them within twelve months of the withdrawal of the designation.

在第一子段中所述的情况下，证书覆盖的器械制造商（有其自己商业注册地）在成员国的医疗器械主管机构可将证书的临时有效期进一步延长 3 个月（总共不超过 12 个月）。 In the circumstances referred to in the first subparagraph, the competent authority for medical devices of the Member State in which the manufacturer of the device covered by the certificate has its place of business may extend the provisional validity of the certificates for further periods of three months, which altogether shall not exceed twelve months.

承担受委任变更影响公告机构职能的主管机构或公告机构，应立即通知委员会、其他成员国及其他相关公告机

构。The authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.

第 47 条 Article 47

对公告机构资质的挑战

Challenge to the competence of notified bodies

1. 委员会联合 MDCG 会对引发关注的公告机构或其一个 /多个分支机构或分包商连续履行附录 VII 要求或其应承担义务的情况进行调查。应确保负责公告机构的主管机构接到通知并有合适的机会对关注问题进行调查。 The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VII or the obligations to which they are subject. It shall ensure that the relevant authority responsible for notified bodies is informed and is given an opportunity to investigate those concerns.

2. 公告成员国应按要求向委员会提供有关委任公告机构所发公告的所有信息。 The notifying Member State shall provide the Commission, on request, with all information regarding the designation of the notified body concerned.

3. 在合理关注公告机构或其分支机构或分包商符合附录 VII 所列要求的现状和主管机构的调查未能完全解决关注问题时，或应主管机构要求，委员会可联合 MDCG 启动（如适用）第 39(3)和(4)条所述的评估流程。此外，该报告和评估流程的结果应遵循第 39 条的原则。另外，根据问题的严重程度，委员会和 MDCG 可要求负责公告机构的主管机构允许来自第 40 条名单中最多两位专家参与现场评估，作为第 44 条所述计划检查和评估活动以及第 44（4）条所述年度评估计划的一部分。 The Commission, in conjunction with the MDCG, may initiate, as applicable, the assessment procedure described in Article 39(3) and (4), where there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VII and where the investigation by the authority responsible for notified bodies is not deemed to have fully addressed the concerns or upon request of the authority responsible for notified bodies. The reporting and outcome of that assessment shall follow the principles of Article 39. Alternatively, depending on the severity of the issue, the Commission, in conjunction with the MDCG, may request that the authority responsible for notified bodies allow the participation of up to two experts from the list established pursuant to Article 40 in an on-site assessment as part of the planned monitoring and assessment activities in accordance with Article 44 and as outlined in the annual assessment plan described in Article 44(4).

4. 若委员会确定公告机构不再符合其委任要求，应当相应地通知公告成员国，要求其采取必要的纠正措施，包括暂停、限制或必要时撤消委任。 Where the Commission ascertains that a notified body no longer meets the requirements for its designation, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary.

凡成员国未能采取必要的纠正措施，委员会可通过实施细则来暂停、限制或撤销公告。应按照第 114(3)条的审查流程通过这些实施细则。 应当通知有关成员国相关决议， 并更新 NANDO 和第 57 条中所述的电子系统。 Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the designation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). It shall notify the Member State concerned of its decision and update NANDO and the electronic system referred to in Article 57.

5. 委员会应确保对调查过程中获得的所有保密信息保密。 The Commission shall ensure that all confidential information obtained in the course of its investigations is treated accordingly.

第 48 条 Article 48

同行评审和负责公告机构的主管机构之间的经验交流

Peer review and exchange of experience between authorities responsible for notified bodies

1. 委员会应为负责公告机构的主管机构提供经验交流及实践合作的机会。该交流应包括以下内容： The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the authorities responsible for notified bodies. Such exchange shall cover elements including:

(a) 负责公告机构主管机构活动的最佳实践文件的制定； development of best practice documents relating to the activities of the authorities responsible for notified bodies;

(b) 与本法规实施相关的公告机构指导性文件的制定； development of guidance documents for notified bodies in relation to the implementation of this Regulation;

(c) 第 40 条所述专家的培训和资格认定； training and qualification of the experts referred to in Article 40;

(d) 监控公告机构委任和公告的变更以及公告机构之间证书撤销和转让的动态； monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;

(e) 监控第 42（13）条所述的范围代码的申请和使用； monitoring of the application and applicability of scope codes referred to in Article 42(13);

(f) 制定主管机构与委员会之间的同行评审机制； development of a mechanism for peer reviews between authorities and the Commission;

(g) 向公众传播主管机构和委员会对公告机构的监督和监管活动的方法。 methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies.

2. 负责公告机构的主管机构应根据本条第 1 段制定的机制每三年参与一次同行评审。该审查通常应在第 39 条所述的现场联合评估同时进行，另外主管机构可选择进行该审查并作为第 44 条所述的其监管活动的一部分。 The authorities responsible for notified bodies shall participate in a peer review every third year through the mechanism developed pursuant to paragraph 1 of this Article. Such reviews shall normally be conducted in parallel with the on-site joint assessments described in Article 39. Alternatively, an authority may make the choice of having such reviews take place as part of its monitoring activities referred to in Article 44.

3. 委员会应参与组织并为同行评审机制的实施提供支持。 The Commission shall participate in the organisation and provide support to the implementation of the peer review mechanism.

4. 委员会应撰写同行评审活动的年度总结报告并予以公布。 The Commission shall compile an annual summary report of the peer review activities, which shall be made publicly available.

5. 委员会可通过实施细则，采取措施限定本条第 1 段所述的同行评审机制详细安排和相关文件、培训和资格认定。应按照第 114(3)条中所述的审查流程通过这些实施细则。 The Commission may, by means of implementing acts, adopt measures setting out the detailed arrangements and related documents for the peer review mechanism and training and qualification as referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 49 条 Article 49

公告机构的协调

Coordination of notified bodies

委员会应确保公告机构之间有适当的协调和合作，并且在医疗器械（包括体外诊断医疗器械）领域内以公告机构协调组的形式进行。该协调组应定期会面，至少每年一次。 The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including in vitro diagnostic medical devices. This group shall meet on a regular basis and at least annually.

根据本法规，公告机构应参与该协调组的工作。

The bodies notified under this Regulation shall participate in the work of that group.

委员会可建立公告机构协调组的具体安排。

The Commission may establish the specific arrangements for the functioning of the coordination group of notified bodies.

第 50 条 Article 50

收费标准列表 **List of standard fees**

公告机构应制定并公开其所开展的符合性评估活动的收费标准列表。 Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available.

第 V 章 CHAPTER V

分类和符合性评估 CLASSIFICATION AND CONFORMITY ASSESSMENT

第 1 节 SECTION 1

分类 Classification

第 51 条 Article 51

器械分类 **Classification of devices**

1. 根据器械的预期用途和其固有风险， 医疗器械应分为 I、IIa、IIb 和 III 类。分类应按照附录 VIII 规定进行。 Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII.

2. 制造商和相关公告机构之间因应用附录 VIII 而产生的任何争议， 应提交至制造商注册营业所在成员国主管机构做出裁定。对于未在欧盟注册营业地址也未指定授权代表的制造商，应提交至附录 IX 第 2.2 节（b）点最后一项中所述的授权代表注册营业所在成员国的主管机构。当相关公告机构处于非制造商所在成员国时，主管机构应在与委任该公告机构的成员国主管机构咨询后方可通过其决议。 Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State in which the authorised representative referred to in the last indent of point (b) of the second paragraph of Section 2.2 of Annex IX has its registered place of business. Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

具有营业注册地的制造商所在成员国的主管机构应将其决议告知 MDCG 及委员会。该决议可根据要求提供。The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request

3. 应成员国要求，委员会应在咨询 MDCG 后通过实施细则，并就以下项目做出决议： At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) 对指定器械、类别或器械组使用附录 VIII ，做出此类器械分类决议； application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) 因公共健康原因，根据新的科学证据、或警戒和市场监管活动中获取的任何信息，通过豁免附录 VIII ，为器械、 类别或器械组进行重新分类。 that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. 委员会也可在咨询 MDCG 后，通过实施细则自行决议第 3 段（a）和（b）点所述的问题。 The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.

5. 为保证附录 VIII 的统一适用，并考虑到相关科学委员会的相关科学观点，委员会可采取实施细则，以解决分歧和实际应用的问题。 In order to ensure the uniform application of Annex VIII, and taking account of the relevant scientific opinions of the relevant scientific committees, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application.

6. 本条第 3、4 和 5 段中所述的实施细则应按照第 114(3)条的审查流程予以通过。 The implementing acts referred to in paragraphs 3, 4 and 5 of this Article shall be adopted in accordance with the examination procedure referred to in Article 114(3)

第 2 节 SECTION 2

符合性评估 Conformity assessment

第 52 条 Article 52

符合性评估流程 Conformity assessment procedures

1. 在器械投放市场之前，制造商应对该器械符合性进行评估。符合性评估流程见附录 IX 至 XI 。 Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

2. 在投放使用前，制造商应按照附录 IX 至 XI 中的符合性评估流程对未投放市场的器械进行符合性评估。 Prior to putting into service a device that is not placed on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI 。

3. III 类器械（非客户定制器械或研究器械）的制造商应依据附录 IX 中符合性评估的规定进行符合性评估。另外，制造商也可选择附录 X 规定的符合性评估联合附录 XI 规定的符合性评估进行符合性评估。 Manufacturers of class III devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Annex X coupled with a conformity assessment as specified in Annex XI.

4. IIb 类器械（非客户定制器械或研究器械）的制造商应依据附录 IX 第 I 章和第 III 章规定的符合性评估（包括附录第 4 节中规定的对各同类器械组中至少一个代表性器械的技术文件评估）进行符合性评估。 Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

然而对于 IIb 类可植入器械，但不包括缝线、 U 形钉、牙齿填充物、牙套、齿冠、螺钉、楔子、牙板、金属丝、针、小夹和连接体， 附录 IX 第 4 节中所规定的技术文件评估应适用于每一器械。 However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

另外，制造商也可选择按照附录 X 规定的形式审核联合附录 XI 规定的基于产品符合性验证的符合性评估进行符合性评估。 Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.

5. 如理由充分，鉴于与本条第 4 段列表中器械所使用的成熟技术相似，此类技术可用于其他 IIb 类可植入器械，为保护患者、 使用者或其他人员或其他方面的卫生安全， 委员会应有权依照第 115 条以授权法案形式将其他 IIb 类植入器械添加到列表或从列表中删除，从而达到修订列表的目的。 Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom.

6. IIa 类器械（非客户定制或研究器械）制造商应根据附录 IX 第 I 和 III 章规定的质量管理体系接受符合性评估，并应对各器械类别中至少一个代表性器械的该附录第 4 节所述技术文件进行评估。 Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices.

此外， 制造商也可选择根据附录 II 和 III 及基于附录 XI 第 10 节或第第 18 节产品符合性验证的符合性评估起草技术文件。该技术文件评估应至少适用各器械类别中至少一个代表性器械。 Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.

7. I 类器械（非客户定制或研究器械）制造商在制定附录 II 和 III 规定的技术文件后，须通过签发第 19 条中的 EU 符合性声明，以声明其产品的符合性。若这些器械在无菌状态下投放市场，具有测定功能或为可重复使用手术器械，制造商应采用附录 IX 第 I 章和第 III 章或附录 XI 第 A 部分所述程序。但公告机构的介入应限于： Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III. If those devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI. However, the involvement of the notified body in those procedures shall be limited:

(a) 若此类器械在无菌状态下投放市场， 则涉及建立、 保障和保持无菌条件。 in the case of devices placed on

the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions;

(b) 若此类器械具有测定功能，则涉及器械符合计量要求的情况。 in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements;

(c) 若是可重复使用手术器械，则涉及器械的可重复利用，特别是清洗、消毒、杀菌、维护、功能测试和相关使用说明书。 in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

8. 客户定制器械的制造商应遵循附录 XIII 所述程序并按照该附录第 1 节规定起草声明后再将该器械投放市场。 Manufacturers of custom-made devices shall follow the procedure set out in Annex XIII and draw up the statement set out in Section 1 of that Annex before placing such devices on the market.

根据第一子段的适用程序， III 类客户定制植入器械的制造商应遵循附录 IX 第 I 章规定的符合性评估流程。 此外，制造商根据附录 XI 第 A 部分规定，可选择应用符合性评估。 n addition to the procedure applicable pursuant to the first subparagraph, manufacturers of class III custom-made implantable devices shall be subject to the conformity assessment as specified in Chapter I of Annex IX. Alternatively, the manufacturer may choose to apply a conformity assessment as specified in Part A of Annex XI.

9. 除根据本条第 3、4、6 或 7 段所适用的程序外，在第 1（8）条所指器械的情况下，附录 IX 第 5.2 节或附录 X 第 6 节所规定的程序应适用。 In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices referred to in the first subparagraph of Article 1(8), the procedure specified in Section 5.2 of Annex IX or Section 6 of Annex X, as applicable, shall also apply

10 除根据本条第 3、4、6 或 7 段所适用的程序外，如根据本法规所涵盖的符合第 1（6）条（ f）点或（ g）点及第 1（10）条第一子段的器械， 附录 IX 第 5.3 节或附录 X 第 6 节规定的程序也应当适用 （如适当）。In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7 of this Article, in the case of devices that are covered by this Regulation in accordance with point (f) or (g) of Article 1(6) and with the first subparagraph of Article 1(10), the procedure specified in Section 5.3 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

11. 除根据本条第 3、4、6 或 7 段所适用的程序外，在器械通过体孔将包含的药物或合成物送入人体或通过涂抹于皮肤后被人体吸收或在局部扩散的情况下，附录 IX 第 5.4 节或附录 X 第 6 节的规定也应当适用（如适当） 。 In addition to the procedures applicable pursuant to paragraph 3, 4, 6, or 7, in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the procedure specified in Section 5.4 of Annex IX or Section 6 of Annex X, as applicable, shall also apply.

12. 成员国境内的公告机构可决议， 与第 7 和 9 至 11 段所述程序相关的所有或某些文件， 其中包括技术文件、 审计、评估和检验报告，并应当使用相关成员国的欧盟官方语言编写。在无此类要求情况下，这些文件应使用公告机构可接受的欧盟官方语言编写。 The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 7 and 9 to 11 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body.

13. 研究器械应遵守第 62 至 81 条的要求。 Investigational devices shall be subject to the requirements set out in Articles 62 to 81.

14. 委员会可通过实施细则，规定详细安排和程序等问题，以确保公告机构在以下方面协调应用符合性评估流程：
The Commission may, by means of implementing acts, specify detailed arrangements and procedural aspects with a view to ensuring the harmonised application of the conformity assessment procedures by the notified bodies for any of the following aspects:

(a) 附录 IX 第 2.3 节和第 3.5 节第三段有关 IIa 类器械和 IIb 类器械以及附录 XI 第 10.2 节有关 IIa 类器械代表性技术文件评估频率和抽样评估结果。 the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in the third paragraph of Section 2.3 and in Section 3.5 of Annex IX in the case of class IIa and class IIb devices, and in Section 10.2 of Annex XI in the case of class IIa devices;

(b) 公告机构按照附录 IX 第 3.4 节进行的突击现场审核和抽样测试的最低频率，应考虑风险级别和器械的类型；the minimum frequency of unannounced on-site audits and sample tests to be conducted by notified bodies in accordance with Section 3.4 of Annex IX, taking into account the risk-class and the type of device;

(c) 公告机构根据附录 IX 第 3.4 节和第 4.3 节、附录 X 第 3 节以及附录 XI 第第 15 节规定通过抽样测试、技术文件评估和形式检验而进行物理测试、实验室测试或其他测试。 the physical, laboratory or other tests to be carried out by notified bodies in the context of sample tests, assessment of the technical documentation and type examination in accordance with Sections 3.4 and 4.3 of Annex IX, Section 3 of Annex X and Section 15 of Annex XI.

应按照第 114(3)条中述及的审查规程通过这些第一子段中所述的实施细则。 The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 53 条 Article 53

公告机构参与符合性评估流程

Involvement of notified bodies in conformity assessment procedures

1. 凡符合性评估流程需要公告机构的参与，制造商可向其选择的公告机构申请，前提是已委任选定公告机构进行有关类型器械的符合性评估活动。 对于同一符合性评估流程， 制造商无法向其他公告机构平行提出同一份申请。
Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned. The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

2. 在做出关于符合性评估决议前， 有关公告机构应通过第 57 条中所述的电子系统通知给其他公告机构已撤销申请的制造商。 The notified body concerned shall, by means of the electronic system referred to in Article 57, inform the other notified bodies of any manufacturer that withdraws its application prior to the notified body's decision regarding the conformity assessment.

3. 根据第 1 段规定申请公告机构时，制造商在该公告机构决议前应声明其已经撤销了其他公告机构的申请，并提供已被其他公告机构拒绝的同一符合性评估的前申请信息 When applying to a notified body under paragraph 1, manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body and provide information about any previous application for the same conformity assessment that has been refused by another notified body.

4. 公告机构可要求制造商提供任何信息或数据，以适当开展选定的符合性评估流程。 The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure.

5. 公告机构以及公告机构人员必须具备执行符合性评估活动的最高级别职业操守、必备技术及特定领域的科学技能，并且能够抵抗一切压力和诱惑，特别是可能会影响其判断或符合性评估活动结果的资金问题，尤其是对于这些活动的结果有利益关系的个人或集体。 Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.

第 54 条 Article 54

特定 **III** 类器械和 **IIb** 类器械的临床评价咨询流程

Clinical evaluation consultation procedure for certain class III and class IIb devices

1. 除了根据第 52 条的适用程序外，公告机构在执行下列器械的符合性评估时，应遵循附录 IX 第 5.1 节或附录 X 第 6 节规定的临床评价咨询流序 （如适用）：In addition to the procedures applicable pursuant to Article 52, a notified body shall also follow the procedure regarding clinical evaluation consultation as specified in Section 5.1 of Annex IX or as referred to in Section 6 of Annex X, as applicable, when performing a conformity assessment of the following devices:

   (a) III 类可植入器械；和 class III implantable devices, and

   (b) 附录 VIII 第 6.4 节（规则 12）所述的用于给予和 /或清除药品的 IIb 类有源器械。 class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12)

2. 第 1 段中所述的流程不用于以下所述的器械： The procedure referred to in paragraph 1 shall not be required for the devices referred to therein:

   （a） 根据本法规更新颁发证书的情况； in the case of renewal of a certificate issued under this Regulation;

   （b） 由同一制造商将已投放市场的器械进行改进后设计出的具有相同预期用途的器械，若制造商已证明达到公告机构满意程度， 则该改进不得对器械收益 /风险比产生不利影响。 where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or

   （c） 有关器械类型或种类的临床评价原则已写入第 9 条所所述的 CS 中，且公告机构证实制造商器械临床评价符合其相关的临床评价 CS 要求。 where the principles of the clinical evaluation of the device type or category have been addressed in a CS referred to in Article 9 and the notified body confirms that the clinical evaluation of the manufacturer for this device is in compliance with the relevant CS for clinical evaluation of that kind of device.

3. 公告机构应依据第 57 条（无论本条第 1 段中所述的程序是否适用） 规定系统通知主管机构、 负责公告机构的主管机构和委员会。该通知应随附临床评估的评定报告。 The notified body shall notify the competent authorities, the authority responsible for notified bodies and the Commission through the electronic system referred to in Article 57 of whether or not the procedure referred to in paragraph 1 of this Article is to be applied. That notification shall be accompanied by the clinical evaluation assessment report.

4. 委员会应起草一份符合附录 IX 第 5.1 节或附录 X 第 6 节程序的器械年度总结。 该年度总结应包括本条第 3 段和附录 IX 第 5.1 节（ e）点规定的公告决议以及公告机构在未听从专家小组建议情况下而编入的列表。委员会应将该总结提交至欧洲议会、理事会和医疗器械协调小组。 The Commission shall draw up an annual overview of devices which have been subject to the procedure specified in Section 5.1 of Annex IX and referred to in Section 6 of Annex X. The annual overview shall include the notifications in accordance with paragraph 3 of this Article and

point (e) of Section 5.1 of Annex IX and a listing of the cases where the notified body did not follow the advice from the expert panel. The Commission shall submit this overview to the European Parliament, to the Council and to the MDCG.

5. 委员会应 2025 年 5 月 27 日之前起草关于本条实施情况的报告，并将其提交欧洲议会和理事会。提交报告中应包括年度总结和 MDCG 提出的相关可用建议。根据本报告，委员会应酌情提出修订本法规的建议。 The Commission shall by 27 May 2025 draw up a report on the operation of this Article and submit it to the European Parliament and to the Council. The report shall take into account the annual overviews and any available relevant recommendations from the MDCG. On the basis of that report the Commission shall, if appropriate, make proposals for amendments to this Regulation.

第 55 条 Article 55

特定 **III** 类器械和 **IIb** 类器械的符合性评估的审查机制

Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

1. 公告机构应通知已授予器械证书的主管机构，其中符合性评估已根据第 54（1）条执行。应根据第 57 条所所述的电子系统发出此类通知并包括符合第 32 条的安全和临床性能信息总结、公告机构的评估报告、附录 I 第 23.4 节所所述的使用说明书、附录 IX 第 5.1 节或附录 X 第 6 节所所述的专家小组科学建议（如适用）以及在公告机构和专家小组产生意见分歧的情况下，应包括充分理由）。 A notified body shall notify the competent authorities of certificates it has granted to devices for which the conformity assessment has been performed pursuant to Article 54(1). Such notification shall take place through the electronic system referred to in Article 57 and shall include the summary of safety and clinical performance pursuant to Article 32, the assessment report by the notified body, the instructions for use referred to in Section 23.4 of Annex I, and, where applicable, the scientific opinion of the expert panels referred to in Section 5.1 of Annex IX or Section 6 of Annex X, as applicable. In the case of divergent views between the notified body and the expert panels, a full justification shall also be included.

2. 主管机构以及委员会（在适当情况下）可根据合理顾虑，根据第 44、45、46、47 或 94 条要求开展进一步程序，并在必要时，根据第 95 和 97 条采取适当措施。 A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 44, 45, 46, 47 or 94 and, where deemed necessary, take appropriate measures in accordance with Articles 95 and 97.

3. MDCG 以及委员会（在适当情况下）可根据合理顾虑，要求专家小组就任何器械的安全性和性能要求给出科学建议。 The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.

第 56 条 Article 56

符合性证书

Certificates of conformity

1. 由公告机构根据附录 IX、X 和 XI 所颁发的证书应使用该公告机构所在成员国确定的欧盟官方语言或此公告机构可接受的欧盟官方语言编写。该证书的最低应有内容列于附录 XII 中。 The certificates issued by the notified bodies in accordance with Annexes IX, X and XI shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates shall be as set out in Annex XII.

2. 该证书的有效期为其列明的期限，不得超过五年。 制造商可申请延长证书的有效期，但每次延期不得超过五年，同时需要按照适用的符合性评估流程重新评估。证书的任何补充内容应与其补充的证书具有相同有效期。 The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the

manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.

3. 公告机构可限制器械应用于某些特定患者的预期用途, 或要求制造商承担按照附录 XIV 第 B 部分进行的 PMCF 研究。 Notified bodies may impose restrictions to the intended purpose of a device to certain groups of patients or require manufacturers to undertake specific PMCF studies pursuant to Part B of Annex XIV.

4. 若公告机构认定制造商不再满足本法规的要求，需考虑均衡原则，暂停或撤销颁发的证书或对其施加限制，除非制造商在公告机构规定的时间内采取合适的纠正措施保证遵守要求。该公告机构需给出其所作决议的理由。
Where a notified body finds that the requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.

5. 公告机构应将所签发证书的相关信息录入第 7 条所述电子系统，包括修订和补充以及证书的暂停、恢复、撤销或拒绝， 和对证书的限制。 此信息应向公众开放。 The notified body shall enter in the electronic system referred to in Article 57 any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. Such information shall be accessible to the public.

6. 随着技术进步，委员会应有权按照第 115 条采取纠正措施或按照附录 XII 补充证书的最低应有内容。 In the light of technical progress, the Commission is empowered to adopt delegated acts in accordance with Article 115 amending the minimum content of the certificates set out in Annex XII.

第 57 条 Article 57

公告机构和符合性证书的电子系统

Electronic system on notified bodies and on certificates of conformity

1. 在咨询 MDCG 后, 委员会应建立并管理电子系统来整理和处理以下信息； The Commission, after consulting the MDCG, shall set up and manage an electronic system to collate and process the following information:

(a) 第 37（3）条所述分支机构名单； the list of subsidiaries referred to in Article 37(3);

(b) 第 40（2）条所述专家名单； the list of experts referred to in Article 40(2);

(c) 第 42（10）条所述通知相关信息和第 46（2）所述的修订公告； the information relating to the notification referred to in Article 42(10) and the amended notifications referred to in Article 46(2);

(d) 第 43(2)条所述公告机构名单； the list of notified bodies referred to in Article 43(2);

(e) 第 44（12）条所述总结报告； the summary of the report referred to in Article 44(12);

(f) 第 54（3）条和第 55(1)条中所述的有关符合性评估和证书的通知； the notifications for conformity assessments and certificates referred to in Articles 54(3) and 55(1);

(g) 在第 53(2)条和附录 VII 第 4.3 节中所述证书申请撤回或拒绝； withdrawal or refusals of applications for the certificates as referred to in Article 53(2) and Section 4.3 of Annex VII;

(h) 在第 56(5)条中所述证书相关信息； the information regarding certificates referred to in Article 56(5);

(i) 第 32 条所述安全和临床性能总结。 the summary of safety and clinical performance referred to in Article 32.

2. 电子系统整理和处理的信息应由各成员国主管机构、委员会访问，公告机构（适用时）或本法规另有规定或第 2017/746 号法规应向公众开放。 The information collated and processed by the electronic system shall be

accessible to the competent authorities of the Member States, to the Commission, where appropriate to the notified bodies and where provided elsewhere in this regulation or in Regulation (EU) 2017/746 to the public

第 58 条 Article 58

公告机构的自愿变更

Voluntary change of notified body

1. 对于同一器械的符合性评估，若制造商终止与一家公告机构的合同，而与另一家公告机构签订合同，公告机构的详细安排需在制造商与即将达成协议的公告机构以及（如可行）即将终止协议的公告机构间的协议中明确定义。本协议应至少包括以下几个方面： In cases where a manufacturer terminates its contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the detailed arrangements for the change of notified body shall be clearly defined in an agreement between the manufacturer, the incoming notified body and, where practicable the outgoing notified body. That agreement shall cover at least the following aspects:

(a) 即将终止协议的公告机构颁发的证书失效日期； the date on which the certificates issued by the outgoing notified body become invalid;

(b) 在此之前，即将终止协议的公告机构的标识号需要在制造商提供的信息包括任何宣传资料 the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) 文件传输，包括机密性方面和产权； the transfer of documents, including confidentiality aspects and property rights;

(d) 在此之后，即将终止协议的公告机构的符合性评估任务委托给即将达成协议的公告机构的日期； the date after which the conformity assessment tasks of the outgoing notified body is assigned to the incoming notified body;

(e) 即将终止协议的公告机构负责的最后一个序号或批号。 the last serial number or lot number for which the outgoing notified body is responsible.

2. 在失效日期当日，即将终止协议的公告机构应撤销它为相关器械颁发的证书。 The outgoing notified body shall withdraw the certificates it has issued for the device concerned on the date on which they become invalid.

第 59 条 Article 59

符合性评估流程的豁免

Derogation from the conformity assessment procedures

1. 通过豁免第 52 条，任何主管机构在正当理由要求下，可在成员国境内授权将特定器械的投放市场或投入使用，而无需等待该条所述程序的实施，但其使用应有利于公共健康及患者安全和健康。 By way of derogation from Article 52, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.

2. 该成员国应通知委员会和其他成员国任何授权器械投放市场和投入运行的决议，此决议按照第 1 段中此类授权得到批准使用而不是仅供单一患者使用。 The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.

3. 在按照本条第 2 段发布通知后，委员会针对公共健康或患者安全或健康的特殊情况，可通过实施细则，在一定程度上延长成员国根据本条第 1 段在欧盟境内授权的时限，并设置此器械可投放市场或投入使用的条件。此外，应按照第 114(3)条中述及的审查规程通过这些实施细则。 Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

若存在攸关人类健康与安全的紧迫性理由，委员会应按照第 114(4)条所述的程序立即采取适用的实施细则。 On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4).

第 60 条 Article 60

自由销售证书

Certificate of free sale

1. 为出口目的，应制造商或授权代表要求，制造商或授权代表注册地点所在成员国，需签发一份自由销售证书，声明制造商或授权代表（视情况而定）在其领域具有营业注册地，并且根据此法规，带有 CE 标记的上述器械可在欧盟市场上销售。自由销售证书应在第 29 条规定下的 UDI 数据库中列明器械的基本 UDI-DI 。若公告机构颁发了第 56 条所述证书，则自由销售证书应当依据附录 XII 第 II 章第 3 节列出的公告机构颁发唯一编号标识的此证书。 For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 29. Where a notified body has issued a certificate pursuant to Article 56, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.

2. 委员会可通过实施细则，建立一个自由销售证书模版，其中考虑到自由销售证书的国际使用惯例。应按照第 114(2)

条中述及的咨询规程通过这些实施细则。 The Commission may, by means of implementing acts, establish a model for certificates of free sale, taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 114(2).

第 **VI** 章

临床评价和临床研究

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

第 61 条 Article 61

临床评价 **Clinical evaluation**

1. 在达到该器械预期用途的正常条件下，应证明符合附录 I 所所述的通用安全能要求，且附录 I 第 1 节和第 8 节所所述的不良副作用评估和收益 /风险比可接受性，均应依据临床数据所提供的充分的临床证据包含附录 III 规定的相关数据（如适用） 。Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

   制造商应规定并证明临床证据的等级足以证明符合通用安全与性能相关的基本要求。该临床证据等级应适合器械及其预期用途的特性。 The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

   为此，制造商应根据本法规及附录 XIV 第 A 部分计划、实施并用文件记录临床评价。 To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

2. 对于第 54（1）条（ b）点中所述的所有 III 类和 IIb 类器械，制造商在临床评价和 /或研究前依据第 106 条所述的程序咨询专家小组，目的旨在审查制造商的预期临床用途和临床研究方案。制造商应适当考虑专家小组发表的意见。此外，这些考虑因素应记录在本条第 12 段所述的临床评价报告中。 For all class III devices and for the class IIb devices referred to in point (b) of Article 54(1), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel as referred to in Article 106, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report referred to in paragraph 12 of this Article.

   制造商可能无法从专家小组对任何未来符合性评估流程表达意见中取得任何权利。 The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure.

3. 临床评价应遵循以下明确规定且方法得当的程序： A clinical evaluation shall follow a defined and methodologically sound procedure based on the following:

   (a) 目前涉及器械安全性能、设计特点和预期用途的科学文献关键评估如可用，则满足下列条件： a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied:

      - 依据附录 XIV 第 3 节，表明用于预期用途临床评价的器械等同于与数据相关的器械，

        it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with Section 3 of Annex XIV, and

- 数据充分证明符合相关的通用安全能要求； the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) 所有可用的临床研究结果的关键评估应依据第 62 条至 80 条、依据第 81 条和附录 XV 所采用的法案规定适当考虑是否进行研究。 a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under Articles 62 to 80, any acts adopted pursuant to Article 81, and Annex XV; and

(c) 为上述目的考虑替代当前可用的治疗方案 （如有）。a consideration of currently available alternative treatment options for that purpose, if any.

4. 对于可植入器械和 III 类器械，应进行临床研究，除非： In the case of implantable devices and class III devices, clinical investigations shall be performed, except if:

- 该器械由同一制造商对已投放市场的器械进行改进， the device has been designed by modifications of a device already marketed by the same manufacturer,
- 依据附录 XIV 第 3 节规定，已改进的器械经制造商证明后等同于投放市场的器械，且此证明已得到公告机构认可，及 the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and
- 对投放市场的器械进行临床评价以证明已改进的器械符合相关的安全性能要求。 the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

在这种情况下，公告机构检查发现 PMCF 计划很合适且其中包括上市后研究，以证明器械的安全性能。

此外，临床研究无需在第 6 段所所述的情况下执行。 In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

5. 依据第 4 段规定， 制造商生产出的器械经证实等同于已投放市场的器械 （不属于同一制造商生产） ，除此条所要求的内容外，若以下条件均满足，则无需进行临床研究： A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

- 在这两个制造商拟定合同的适当位置明确允许第二种器械制造商在现有基础上全权使用技术文件。 the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and
- 原始临床评价已依照本法规要求完成， the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

且第二种器械制造商向公告机构提供其明确证据 and the manufacturer of the second device provides clear evidence thereof to the notified body.

6. 依据第 4 段执行临床研究的要求不适用于可植入器械和 III 类器械： The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) 此类器械依据第 90/385/EEC 号指令或第 93/42/EEC 号指令已合法投放市场或投入使用，其临床评价： which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

- 基于足够的临床数据 is based on sufficient clinical data, and
- 符合此类器械临床评价相关产品 CS；或 is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) 针对缝线、 U 形钉、牙齿填充物、牙套、齿冠、螺钉、楔子、牙板、金属丝、针、小夹和连接体而进行的临床评价均应建立在充分的临床数据上且符合相关的特定产品 CS。 that are sutures, staples, dental

fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

7. 对于因第 4 段的规定而未适用第 6 段的情况，在制造商的临床评价临床评价报告和公告机构的临床研究评估报告中可视为合理。 Cases in which paragraph 4 is not applied by virtue of paragraph 6 shall be justified in the clinical evaluation report by the manufacturer and in the clinical evaluation assessment report by the notified body.

8. 若理由充分，则对于具有在其他器械中使用与本条第 6 段（b）点列表中豁免器械所用技术类似技术， 或出于保障患者、使用者或其他个人的健康和安全或公众健康其他方面的考虑，委员会有权根据第 115 条，授权将其他类型的可植入器械或 III 类器械添加到列表中或从中移除，并修订第 52（4）第二子段和本条第 6 段（b）点中所述的豁免器械列表。 Where justified in view of well-established technologies, similar to those used in the exempted devices listed in point (b) of paragraph 6 of this Article, being used in other devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list of exempted devices referred to in the second subparagraph of Article 52(4) and in point (b) of paragraph 6 of this Article, by adding other types of implantable or class III devices to that list or removing devices therefrom.

9. 对于附录 XVI 所列不带有医学目的产品， 本章和附录 XIV 和附录 XV 中要求说明的临床疗效应理解为说明该器械性能的要求。有关安全性相关数据的临床评价，包括来自上市后的监管、 PMCF 和具体的临床研究数据（适用时）的数据。 应对这些产品进行临床研究， 除非其具有能够使用现有类似医疗器械临床数据的正当理由。 In the case of the products without an intended medical purpose listed in Annex XVI, the requirement to demonstrate a clinical benefit in accordance with this Chapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.

10. 在不影响第 4 段规定下，若基于临床数据证明其符合通用安全与性能要求的论证不适当，应根据制造商风险管理的结果，考虑该器械与人体间相互影响的具体细节、预期临床性能和制造商要求，为任何此类例外情况给出充分理由。在此情况下，无论是否仅基于非临床研究结果（包括性能评估、台架试验和临床前评估结果）充分论证其符合通用安全与性能要求，制造商应在在附录 II 所指的技术文件中提供适当证明。 Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

11. 根据附录 XIV 第 B 部分计划和第 84 条所所述的上市后监管计划，在整个器械使用寿命期间，应使用制造商实施 PMCF 后取得的临床数据对临床评价及其文件进行更新。 The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

对于 III 类器械和可植入器械，第 32 条中所述的 PMCF 评估报告、安全和临床性能总结（视患者病情）应使用这些数据至少每年更新一次。 For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.

12. 从中得出的临床评价、结果和临床证据应记录在附录 XIV 第 4 节所述的临床评价临床评价报告中（定制器械除外），并作为附录 II 规定的有关器械技术文件的一部分。 The clinical evaluation, its results and the clinical evidence derived from it shall be documented in a clinical evaluation report as referred to in Section 4 of Annex XIV, which, except for custom-made devices, shall be part of the technical documentation referred to in Annex II relating to the device concerned.

13. 若有必要确保附录 XIV 的应用一致性，委员会可充分考虑技术和科学的进展，必要时采取实施细则的措施以解决发生分歧和实际应用中出现的问题。 应按照第 114(3) 条中述及的审查规程实施这些法案。 Where necessary to ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3)

第 62 条 Article 62

执行有关临床研究的一般要求，以证明器械的符合性

General requirements regarding clinical investigations conducted to demonstrate conformity of devices

1. 临床研究应根据第本条和第 63 - 80 条和根据第 81 条采用的法案和附录 XV 进行设计、授权、执行、记录和报告，前提是其出于以下一个或多个目的， 为临床评价的符合性评估而执行： Clinical investigations shall be designed, authorised, conducted, recorded and reported in accordance with the provisions of this Article and of Articles 63 to 80, the acts adopted pursuant to Article 81, and Annex XV, where carried out as part of the clinical evaluation for conformity assessment purposes, for one or more of the following purposes:

(a) 建立和验证设计、生产和组装的器械在正常使用条件下适用于第 2 条（1）点编号（ 1）中所指的一个或多个特定目的，并能够实现制造商规定的预期性能； to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2, and achieves the performance intended as specified by its manufacturer;

(b) 建立和验证制造商规定的器械临床益处； to establish and verify the clinical benefits of a device as specified by its manufacturer;

(c) 建立和验证器械的临床安全性，确定器械在正常使用状态下是否存在任何不良的副作用，并在权衡器械取得的疗效时评估其所构成的风险是否可接受。 to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

2. 若临床研究的申办方不是在欧盟境内成立的，该申办方应当确保有一个在欧盟依法登记成立的自然人或法人作为法定代理人。该法定代理人应负责确保申办方遵守本法规规定的义务，并应成为本法规规定的申办方的所有通信的收件人。 任何与法定代理人的通信均应视为是与申办方的通信。 Where the sponsor of a clinical investigation is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its

legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication with that legal representative shall be deemed to be a communication with the sponsor.

成员国在其领土或第三国领土上单独进行临床研究时可选择不遵循第一子段，只要其保证申办方在其领土上至少设立一个联络人，该联络人应作为本法规规定的申办方的所有通信收件人。 Member States may choose not to apply the first subparagraph to clinical investigations to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical investigation who shall be the addressee for all communications with the sponsor provided for in this Regulation.

3. 临床研究的设计和实施必须在受试者权利、 安全、 尊严和福祉得到保护并且优先于所有其他利益的基础上开展，并且产生的临床数据必须是科学有效、 可靠、 可信的。 Clinical investigations shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests and the clinical data generated are scientifically valid, reliable and robust.

临床研究应获得科学和伦理审查。伦理审查应当由伦理委员会根据国家法律规定执行。各成员国应确保由伦理委员会进行的审查程序与列于本法规的对临床研究授权申请的评估流程是一致的。至少有一个非专业人士参加伦理审查。 Clinical investigations shall be subject to scientific and ethical review. The ethical review shall be performed by an ethics committee in accordance with national law. Member States shall ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Regulation for the assessment of the application for authorisation of a clinical investigation. At least one lay person shall participate in the ethical review.

4. 需在满足以下所有条件的情况下开展第 1 段所述临床研究： A clinical investigation as referred to in paragraph 1 may be conducted only where all of the following conditions are met:

(a) 根据本法规规定，临床研究需受进行临床研究的成员国的主管机构监管，除非另有说明； the clinical investigation is the subject of an authorisation by the Member State(s) in which the clinical investigation is to be conducted, in accordance with this Regulation, unless otherwise stated;

(b) 一个依据国家法律成立的独立的伦理委员会，不能依据国家法律发布对有关整个成员国有效的有关临床研究的负面评价； an ethics committee, set up in accordance with national law, has not issued a negative opinion in relation to the clinical investigation, which is valid for that entire Member State under its national law;

(c) 依据第 2 段，申办方或其法定代理人或联系人应在欧盟境内依法成立； the sponsor, or its legal representative or a contact person pursuant to paragraph 2, is established in the Union;

(d) 按照第 64 至 68 条弱势群体和受试者应得到适当保护； vulnerable populations and subjects are appropriately protected in accordance with Articles 64 to 68;

(e) 对受试者或公众健康的预期利益超过其可预见的风险和不便，并将监控其是否持续符合本条件； the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;

(f) 根据第 63 条，受试者或其法定代理人 （在受试者不能给与知情同意书时） 已给出知情同意书。 the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent in accordance with Article 63;

(g) 向受试者或其法定代理人（在受试者不能给与知情同意书时）提供在需要时可接收更多信息的实体联系方式； the subject or, where the subject is not able to give informed consent, his or her legally

designated representative, has been provided with the contact details of an entity where further information can be received in case of need;

(h) 根据第 95/46/EC 号指令，保障受试者身心健全的权利、 隐私权以及保护自身有关信息权利； the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;

(i) 临床研究应尽可能减少受试者的伴随疼痛、不适、恐惧及其他可预见风险，在临床研究计划中风险阈值和压力水平均经过具体确定并对其进行持续监控； the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;

(j) 具有资质的医生有责任为受试者提供医疗护理，在适当情况下，合资格的牙医或其他任何个人应依法在临床研究情况下提供相关的患者护理；提供给受试者的医疗服务是一个合格的医生的责任，或者在适当的情况下，一个合格的牙科医生或由国家法律授权的任何其他人有权在临床研究条件下提供相关的患者护理；the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other person entitled by national law to provide the relevant patient care under clinical investigation conditions;

(k) 受试者或其法定代理人在参与临床研究时，不会受到不良影响（包括财务方面） ；no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the clinical investigation;

(l) 所述研究器械应符合适用的附录 I 中规定的通用安全与性能要求， 临床研究所涉及的方面除外， 而对于这些方面，应采取各种预防措施以保障受试者的健康和安全。其中包括在适当情况下的技术和生物安全检测和临床前评估，以及职业安全和事故预防领域中的规定，这些应考虑目前最先进的技术； the investigational device(s) in question conform(s) to the applicable general safety and performance requirements set out in Annex I apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;

(m) 符合附录 XV 的要求。 the requirements of Annex XV are fulfilled.

5. 任何受试者或其法定代理人（当受试者无法签署知情同意书时）可在未造成任何损伤且无需提供任何理由的情况下，通过撤销其知情同意书，随时退出该临床研究。在不违反第 95/46/EC 号指令情况下，撤回知情同意书不得影响已经开展的活动以及在撤离知情同意书前已经获得的数据。 Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

6. 研究人员应从事相关成员国承认的职业，并将其在患者护理方面具有必要的科学知识和经验考虑认定为其是否具有作为研究人员的资格。为执行任务，应参与临床研究的其他人员，应当在教育、培训或相关医疗领域和临床研究方法的经验方面具有相应资格。 The investigator shall be a person exercising a profession which is recognised in the Member State concerned as qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care. Other personnel involved in conducting a clinical investigation shall be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

7. 临床研究使用的器械应适用于临床研究，并具备相似预期用途。 The facilities where the clinical investigation is to be conducted shall be suitable for the clinical investigation and shall be similar to the facilities where the device is intended to be used.

第 63 条 Article 63

知情同意

Informed consent

1. 知情同意书须由第 2 段（c）点所述的面试的受试者编写，注明日期并签名，或根据第 2 段，在已正式通知后，受试者或其法定代理人（不能够给出知情同意书时）签署。当受试者不能编写时，可在至少有一个公正见证人在场的情况下，使用适当的替代方法记录，以予以同意。在这种情况下，见证人应在知情同意书上签名并注明日期。应当向受试者或其法定代理人（在受试者不能给与知情同意书时）提供该文件的副本或备案（如适用）已表示给与知情同意书。知情同意书应记录在案。应当给与受试者或其法定代理人充足的时间，来考虑其是否决议参与临床研究。 Informed consent shall be written, dated and signed by the person performing the interview referred to in point (c) of paragraph 2, and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 2. Where the subject is unable to write, consent may be given and recorded through appropriate alternative means in the presence of at least one impartial witness. In that case, the witness shall sign and date the informed consent document. The subject or, where the subject is not able to give informed consent, his or her legally designated representative shall be provided with a copy of the document or the record, as appropriate, by which informed consent has been given. The informed consent shall be documented. Adequate time shall be given for the subject or his or her legally designated representative to consider his or her decision to participate in the clinical investigation.

2. 为获得知情同意书，提供给与受试者或其法定代理人（在受试者不能给与知情同意书时）的信息应至少包括：
Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:

(a) 使受试者或其法定代理人理解： enable the subject or his or her legally designated representative to understand:

(i) 临床研究的性质、 目的、疗效、影响、风险和困难； the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigations;

(ii) 受试者有权利对个人进行保护， 特别是在不产生任何损害的情况下， 可拒绝参与并随时从临床研究中退出而无需提供任何理由； the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;

(iii) 临床研究的实施条件包括临床研究中受试者参与的预期持续时间；和 the conditions under which the clinical investigations is to be conducted, including the expected duration of the subject's participation in the clinical investigation; and

(iv) 可能的治疗替代方案，包括受试者中止参与临床研究时的后续措施； the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;

(b) 保持受试者或她和其指定合法代表全面性、简洁性、清晰性、相关性和理解性； be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) 在事先面试中须提供一位根据国家法律具有合适资格的研究小组成员； be provided in a prior interview

with a member of the investigating team who is appropriately qualified under national law;

(d) 包括在第 69 条中所述的适用的损伤赔偿制度的信息； include information about the applicable damage compensation system referred to in Article 69; and

(e) 包括临床研究在欧盟范围内第 70（1）条中所述的唯一标识号以及依据本条第 6 段有关临床研究结果可用性的信息。 include the Union-wide unique single identification number of the clinical investigation referred to in Article 70(1) and information about the availability of the clinical investigation results in accordance with paragraph 6 of this Article

3. 在第 2 段所指的信息应书面编写并提供给受试者或其法定代理人（当受试者不能够给出知情同意书时） 。 The information referred to in paragraph 2 shall be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.

4. 在第 2 段（c）中所述的面试期间， 应当特别注意具体患者人群及个别受试者的信息需求， 以及提供信息的方式。 In the interview referred to in point (c) of paragraph 2, special attention shall be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information.

5. 在第 2 段（ c）中所述的面试期间，应确保受试者已充分理解相关信息。 In the interview referred to in point (c) of paragraph 2, it shall be verified that the subject has understood the information.

6. 受试者应知晓临床研究报告，并且无论临床研究结果如何，应尽可能在提供总结报告时，提供方便预期使用者理解的总结报告。第 77（5）条关于第 73 条所指的临床研究电子系统中，不论临床研究的结果如何，在有可能的情况下，应尽可能通知其 . The subject shall be informed that a clinical investigation report and a summary presented in terms understandable to the intended user will be made available pursuant to Article 77(5) in the electronic system on clinical investigations referred to in Article 73 irrespective of the outcome of the clinical investigation, and shall be informed, to the extent possible, when they have become available.

7. 在不违背国家法律的前提下，本法规要求，若要参与临床研究，除了法定代理人给与的知情同意书，也需要取得能够得出意见并对给与的信息进行评估的未成年人的同意。 This Regulation is without prejudice to national law requiring that, in addition to the informed consent given by the legally designated representative, a minor who is capable of forming an opinion and assessing the information given to him or her, shall also assent in order to participate in a clinical investigation.

第 64 条 Article 64

针对无行为能力受试者的临床研究

Clinical investigations on incapacitated subjects

1. 对于无行为能力的受试者，在其无行为能力发生前未给出或拒绝给出知情同意书的情况下，除第 62（4）条的规定的条件， 临床研究只有在符合以下所有条件的前提下进行： In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) 已获得了其法定代理人的知情同意书； the informed consent of their legally designated representative has been obtained;

(b) 鉴于其理解能力，无行为能力受试者以合适的方式接收第 63（2）条中所述的信息； the incapacitated subjects have received the information referred to in Article 63(2) in a way that is adequate in view of their capacity to understand it;

(c) 研究员应当尊重一个能够形成观点并对第 63（2）条的信息进行评估的无行为能力受试者明确拒绝参与或在任何时候退出临床研究的意愿； the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) 不得对受试者和其法定代理人使用激励措施或财务利诱，除了对参与临床研究而直接造成的费用和收入损失提出的补偿。 no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) 临床研究对于无行为能力受试者是必不可少的，同等有效性数据不能通过对能够给出知情同意个人的临床研究或其他研究方式获得； the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;

(f) 临床研究与受试者所患疾病直接相关； the clinical investigation relates directly to a medical condition from which the subject suffers

(g) 有科学依据表明， 无行为能力受试者参与临床研究时产生的直接利益将多于其所涉及的风险和负担。 there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.

2. 受试者应尽可能参与知情同意过程。 The subject shall as far as possible take part in the informed consent procedure.

第 65 条 Article 65

针对未成年人的临床研究

Clinical investigations on minors

除了第 62（4）条设定的条件外， 对未成年人的临床研究必须满足以下所有条件时方可开展： A clinical investigation on minors may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) 已获得了其法定代理人的知情同意； the informed consent of their legally designated representative has been obtained;

(b) 未成年人以适应其年龄和心智成熟度的方式接收第 63（2）条所述的信息，由经过培训或对儿童工作有经验的研究人员或研究小组提供； the minors have received the information referred to in Article 63(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;

(c) 研究员应当尊重一个能够形成观点并对第 63（2）条的信息进行评估的未成年人明确拒绝参与或在任何时候退出临床研究的意愿； the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 63(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) 不得对受试者和其法定代理人使用激励措施或财务利诱，除了对参与临床研究而直接造成的费用和收入损失提出的补偿。 no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

(e) 临床研究旨在考察未成年人的某种身体状况下的治疗结果，或者临床研究对于未成年人是否为必需，以验证在

能够给出知情同意个体的临床研究中获得的数据； the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;

(f) 临床研究与涉及的未成年人的身体状况条件直接有关，或本质上，仅能在未成年人身上进行； the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;

(g) 有科学依据表明，未成年人参与临床研究时产生的直接利益将多于其所涉及的风险和负担。 there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved;

(h) 未成年人应以适应其年龄和心理成熟度的方式参与知情同意过程； the minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity;

(i) 若临床研究期间，未成年人达到国家法律规定的法定行为能力年龄，能够给予知情同意书，应当在受试者可继续参加临床研究前取得其明确的知情同意书。 if during a clinical investigation the minor reaches the age of legal competence to give informed consent as defined in national law, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical investigation.

第 66 条 Article 66

针对孕妇或哺乳期妇女的临床研究

Clinical investigations on pregnant or breastfeeding women

除满足第 62（4）条中规定的条件外，还应满足以下所有条件，孕妇或哺乳期的妇女才能参与临床研究： A clinical investigation on pregnant or breastfeeding women may be conducted only where, in addition to the conditions set out in Article 62(4), all of the following conditions are met:

(a) 临床研究可能对有关孕妇或哺乳妇女及其胎儿或新生儿产生直接益处，超过其所承担的风险和负担； the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;

（b） 对进行研究的哺乳期妇女进行特殊照顾以避免对孩子的健康造成任何不利影响；和 where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

（c） 不得对受试者使用激励措施或金钱利诱，除了对参与临床研究而直接造成的费用和收入损失提出的补偿； no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

第 67 条 Article 67

补充国家措施

Additional national measures

成员国可为强制性兵役的服役人员、 因司法判决被剥夺自由而不能参加临床研究的人员或由社区福利院机构收容的人员规定额外措施。 Member States may maintain additional measures regarding persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in clinical investigations, or persons in residential care institutions

第 68 条 Article 68

紧急情况下的临床研究

Clinical investigations in emergency situations

1. 通过豁免第 62（4）条（ f）点，第 64(1)条(a)和(b)一级第 65 条(a)和(b)，在做出受试者入选临床研究的决议后，即可获得参加临床研究的知情同意书，并可给出临床研究信息，前提是根据该临床研究的临床研究计划，该决议是在受试者接受首次干预治疗时做出的，并且须满足以下所有条件： By way of derogation from point (f) of Article 62(4), from points (a) and (b) of Article 64(1) and from points (a) and (b) of Article 65, informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled:

(a) 因突然的危及生命或其他突发性严重身体状况造成的紧急性情况，受试者不能够提供事先知情同意书也不能收到对于临床研究的事先信息； due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;

(b) 参与临床研究对受试者可能产生直接临床益处的期望是具有科学依据，可提高健康质量，缓解遭受的痛苦，或者提高受试者的健康水平， 或提高身体状况的诊断水平； there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

(c) 在治疗窗口期间，向其法定代理人提供所有的事先信息，并获取事先知情同意是不可能的； it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;

(d) 研究者保证其不知道前受试者拒绝参与临床研究； the investigator certifies that he or she is not aware of any objections to participate in the clinical investigation previously expressed by the subject;

(e) 临床研究直接关系到受试者的健康状况，因此在治疗窗口期内得到受试者或其法定代理人的事先知情同意并提供先验信息是不可能，而且临床研究还具有可在紧急情况下单独进行的特性； the clinical investigation relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations

(f) 与受试者条件的标准治疗相比，临床研究可将风险和受试者身上的负担降至最低。 the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

2. 按照本条第 1 段开展干预治疗后， 应根据第 63 条获得知情同意以便受试者能继续参与临床研究， 并且应按照下列规定提供临床研究的相关信息： Following an intervention pursuant to paragraph 1 of this Article, informed consent in accordance with Article 63 shall be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation shall be given, in accordance with the following requirements:

(a) 对无行为能力的受试者及未成年人，研究者应获得其法定代理人的知情同意，且不得无故拖延，并应尽快向受试者及其法定代理人提供第 63（2）条中所述的信息； regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in Article 63(2) shall be given as soon as possible to the subject and to his or her legally designated representative;

(b) 对于其他受试者，研究者应获得受试者或其法定代理人（以较快者为准）的知情同意，不得无故拖延，同时还应尽快向受试者或其法定代理人 （以较快者为准） 提供第 63（2）条中所述的信息。 regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever can be done sooner, and the information referred to in Article 63(2) shall be given as soon as possible to the subject or his or her legally designated representative, as applicable.

在根据 （b）点规定获得法定代理人知情同意书的情况下， 一旦受试者能够自主提供知情同意书， 则应获得其对继续参与临床研究的知情同意书。 For the purposes of point (b) where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical investigation shall be obtained from the subject as soon as he or she is capable of giving informed consent.

3. 如受试者或其法定代理人 （如有）未同意，则应告知其具有反对使用临床研究所得数据的权利。 If the subject or, where applicable, his or her legally designated representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the clinical investigation.

第 69 条 Article 69

损害赔偿 **Damage compensation**

1. 各成员国应确保受试者在其领土上因参与临床研究而受到损害时有完善系统对其进行补偿，该系统的形式应为保险、担保或具有相同功效并且与风险性质及程度相符的类似安排。 Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

2. 申办方和研究者必须在其开展临床研究的成员国中以适用于该国的形式使用第一段中所述的系统。 The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the clinical investigation is conducted.

第 70 条 Article 70

申请临床研究 Application for clinical investigations

1. 临床研究的申办方应向将进行临床研究的成员国（为本条目的，以下简称为“ 相关成员国 ”）提交申请书，并随附附录 XV 第 II 章中所述的文件。 The sponsor of a clinical investigation shall submit an application to the Member State(s) in which the clinical investigation is to be conducted (referred to for the purposes of this Article as ‘ Member State concerned ’) accompanied by the documentation referred to in Chapter II of Annex XV.

申请应通过第 73 条所指的电子系统提交， 该电子系统应为该临床研究产生一个唯一标识号， 其将用于相应临床研究的所有相关沟通中。收到申请之日起 10 天内，相关成员国应按照附录 XV 第 II 章的要求告知申办方该临床研究是否处于本法规范围内，以及申请档案是否完整。 The application shall be submitted by means of the electronic system referred to in Article 73, which shall generate a Union-wide unique single identification number for the clinical investigation, which shall be used for all relevant communication in relation to that clinical investigation. Within 10 days of it receiving the application, the Member State concerned shall notify the sponsor as to whether the clinical investigation falls within the scope of this Regulation and as to whether the application dossier is complete in accordance with Chapter II of Annex XV .

2. 对附录 XV 第 II 章所指的相关文件进行任何修改后的一周内，申办方应在第 73 条所指的电子系统中更新相关数据并使更改的文件清晰可辨。应通过电子系统告知有关成员国数据已更新。 Within one week of any change occurring in relation to the documentation referred to in Chapter II of Annex XV, the sponsor shall update the relevant data in the electronic system referred to in Article 73 and make that change to the documentation clearly identifiable. The Member State concerned shall be notified of the update by means of that electronic system.

3. 当成员国发现提出申请的临床研究未处于本法规范围内或申请未完成，应当通过第 73 条中所述的电子系统通知其申办方，并给出最多十天的时间限制，供申办方表达其意见或完成申请。具有合理理由的情况下，成员国最多可将这一期限延长为 20 天。Where the Member State concerned finds that the clinical investigation applied for does not fall within the scope of this Regulation or that the application dossier is not complete, it shall inform the sponsor thereof and shall set a time limit of maximum 10 days for the sponsor to comment or to complete the application by means of the electronic system referred to in Article 73. The Member State concerned may extend this period by a maximum of 20 days where appropriate.

若申办方在第一子段中所述的期限内未发表意见或完成申请，则该申请将视为失效。若申办方认为申请处于本法规范围内和/或已完成，但相关成员国不同意，则视为申请被拒绝。相关成员国应提供有关此类拒绝申请拒绝申请的上诉程序。 Where the sponsor has not provided comments nor completed the application within the time limit referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers the application does fall under the scope of this Regulation and/or is complete but the Member State concerned does not, the application shall be considered to have been rejected. The Member State concerned shall provide for an appeal procedure in respect of such refusal.

不管临床研究是否处于本法规范围内、申请是否完整，相关成员国均应在收到申办方的意见或所要求的额外信息后五天内通知申办方。 The Member State concerned shall notify the sponsor within five days of receipt of the comments or of the requested additional information, whether the clinical investigation is considered as falling within the scope of this Regulation and the application is complete.

4. 有关成员国还可将第 1 和第 3 段中所述的期限再延长 5 天。The Member State concerned may also extend the period referred to in paragraph 1 and 3 each by a further five days.

5. 根据本章规定，按照第 1 或第 3 段的要求通知申办方的日期应为申请的确认日期。若申办方未收到通知，则确认日期应分别为第 1、3 和 4 段中所所述时间段的最后一天。 For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or 3 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the periods referred to in paragraphs 1, 3 and 4 respectively.

6. 在此期间，申请处于评估状态，成员国可要求申办方提供额外的信息。应当从第一次请求之日起暂停第 7 段（b）点规定到期日期，直至收到相关附加信息。 During the period when the application is being assessed, the Member State may request additional information from the sponsor. The expiry of the period laid down in point (b) of paragraph 7 shall be suspended from the date of the first request until such time as the additional information has been received.

7. 申办方可在下列情况下进行临床研究： The sponsor may start the clinical investigation in the following circumstances:

(a) 对于分类为 I 类的研究型器械或分类为 IIa 和 IIb 的非侵入式器械，除非国家法律另有说明，否则应在第 5 段所述申请验证日期到期后立即执行，但前提是相关成员国伦理委员会未公布根据国家法律对整个成员国的有效的关于临床研究负面评价； in the case of investigational class I devices or in the case of non-invasive class IIa and class IIb devices, unless otherwise stated by national law, immediately after the validation date of the application pursuant to paragraph 5, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation;

(b) 对于除（ a）所所述外的其他研究型器械，只需相关成员国通知其授权的申办方，但前提是相关成员国伦理委员会未公布根据国家法律对整个成员国的有效的有关临床研究的负面评价；且成员国应在第 5 段中所述的确认日期后 45 天内向申办方发出授权通知。 成员国可将此期限延长 20 天以便进行专家咨询。 in the case of investigational devices, other than those referred to in point (a), as soon as the Member State

concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts.

8. 委员会有权按照第 115 条的规定，根据技术进步和全球的监管发展动态，获得授权以修订或补充附录 XV 第 II 章中规定的要求。 The Commission is empowered to adopt delegated acts in accordance with Article 115 amending, in the light of technical progress and global regulatory developments, the requirements laid down in Chapter II of Annex XV.

9. 为确保附录 XV 第 II 章中规定要求的统一适用，委员会可批准实施细则，这在某种程度上解决了发生分歧和实际应用中出现的问题。这些实施细则应当根据第 114(3)中的所述的检查程序予以通过。 In order to ensure the uniform application of the requirements laid down in Chapter II of Annex XV, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 71 条 Article 71

成员国评估

Assessment by Member States

1. 各成员国应确保人员核实和评估流程，或对其进行确定，不得有任何利益冲突，独立于申办方、相关研究者和为临床研究提供资金的自然人或法人，并应免除其他任何不适当的影响。 Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of natural or legal persons financing the clinical investigation, as well as free of any other undue influence.

2. 各成员国应确保评估是由适当数量的具有必要资质和经验的人员共同完成。 Member States shall ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

3. 各成员国应评估临床研究是否已将对受试者或第三人的潜在剩余风险降至最低，并达到风险最小化的标准后，则可权衡其预期的临床益处。此外，审查时应考虑适用的 CS 或协调标准，特别是检查以下要点时： Member States shall assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall, while taking into account applicable CS or harmonised standards, examine in particular:

(a) 除了临床研究已覆盖的方面外，还需考虑具有适用的通用安全与性能要求的研究的器械的法规符合性证据，不管在这些方面的问题上是否已采取任何保护受试者健康和安全的预防措施。其中包括，在适当情况下保证技术和生物安全测试以及临床前评估的实施； the demonstration of compliance of the investigational device(s) with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;

(b) 申办方是否采取了协调标准中说明的风险最小化方案，若申办方未使用协调标准，无论风险最小解决方案是否提供与协调标准一致水平的保护； whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by harmonised standards;

(c) 制定用于研究型器械安全安装、 投入使用和维护的措施的合理性； whether the measures planned for the safe installation, putting into service and maintenance of the investigational device are adequate;

(d) 临床研究所生成数据的可靠性和稳健性，其应将统计方法、研究和方法的设计考虑在内（包括样本大小、比较产品和指标） ;the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;

(e) 是否满足附录 XV 的要求。 whether the requirements of Annex XV are met;

(f) 对于无菌操作器械，制造商灭菌程序、相关调整信息或研究现场必须进行的灭菌程序的验证证据； in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which have to be conducted by the investigation site;

(g) 根据第 2001/83/EC 号指令来源于动物或人体的物质视为医疗产品， 应证明其安全性、 质量和有用性。 the demonstration of the safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products in accordance with Directive 2001/83/EC.

4. 各成员国应拒绝同意临床研究， 若：Member States shall refuse the authorisation of the clinical investigation if:

(a) 根据第 70（1）条递交的申请档案仍不完整； the application dossier submitted pursuant to Article 70(1) remains incomplete;

（b） 该器械或提交的文件，特别是研究计划或研究者手册，与当前的科学技术水平不一致，尤其是临床研究无法提供该器械对受试者或患者有关安全性、性能特征或疗效的证据。 the device or the submitted documents, especially the investigation plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients,

（c） 不满足第 62 条的要求，或 the requirements of Article 62 are not met, or

（d） 根据第 3 段进行的某些评估得出负面结果。 any assessment under paragraph 3 is negative

成员国应根据第一子段提供有关此类拒绝申请的上诉程序。 Member States shall provide for an appeal procedure in respect of a refusal pursuant to the first subparagraph.

第 72 条

临床研究的实施

Conduct of a clinical investigation

1. 申办方和研究者应确保该临床研究符合已批准的临床研究计划。 The sponsor and the investigator shall ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.

2. 为证明受试者的权利、 安全和福利得到保障， 所报告数据可靠且完善， 以及进行的临床研究符合本法规的要求，申办方应当充分监督整个临床研究过程。申办方应评估临床研究中涉及的所有特征，根据评估结果决议监督的范围和性质，其中包括以下特征：

In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical investigation is in compliance with the requirements of this Regulation, the sponsor shall ensure adequate monitoring of the conduct of a clinical investigation. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the clinical investigation including the following:

(a) 临床研究的目的和方法 the objective and methodology of the clinical investigation; and

(b) 正常临床实践干预的偏离程度。 the degree of deviation of the intervention from normal clinical practice.

3. 申办方或研究员应记录、计算、处理和储存所有临床研究信息，（如适用）根据保护个人资料的相关法律，在保护记录机密性和受试者个人资料的同时，对其进行精确的报告、解释和验证。 All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.

4. 应采取适当的技术和组织措施，以保护信息和个人资料免受非法侵入、披露、传播、修改或破坏或意外丢失，尤其是当处理过程需涉及网络传输时。 Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

5. 成员国应在合适水平的研究机构开展审查，以检查是否根据本法规要求及批准的研究计划进行了临床研究。 Member States shall inspect, at an appropriate level, investigation site(s) to check that clinical investigations are conducted in accordance with the requirements of this Regulation and with the approved investigation plan.

6. 申办方应制定紧急情况程序，以便立即识别并在必要时立即召回用于研究的器械。 The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

第 73 条

临床研究电子系统 **Electronic system on clinical investigations**

1. 委员会应与成员国合作设立、管理和维护电子系统： The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

（a） 为临床研究创建第 70（1）条中所述的单个识别号； to create the single identification numbers for clinical investigations referred to in Article 70(1);

（b） 用作第 70、74、75 和 78 条所述临床研究的所有申请或通知提交，以及本文中所有其他数据提交或数据处理的入口位点； to be used as an entry point for the submission of all applications or notifications for clinical investigations referred to in Articles 70, 74, 75 and 78 and for all other submission of data, or processing of data in this context;

（c） 用于按照本法规在成员国之间以及成员国与委员会之间交流有关临床研究的信息，包括第 70 条和第 76 条所述的信息交换； for the exchange of information relating to clinical investigations in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in Articles 70 and 76;

（d） 按照第 77 条由申办方提供信息，包括该条第 5 段所要求的临床研究报告及其总结； for information to be provided by the sponsor in accordance with Article 77, including the clinical investigation report and its summary as required in paragraph 5 of that Article;

（e） 用于报告第 80 条所述的严重不良事件和器械缺陷及相关更新。 for reporting on serious adverse events and device deficiencies and related updates referred to in Article 80.

2. 在设立本条第 1 段所述电子系统时，委员会应确保其与用于根据欧洲议会和理事会第 536/2014 号法规[1]涉及将器械临床研究与临床试验相结合的第 81 条规定的人医疗产品临床试验的欧盟数据库彼此兼容。 When setting up

the electronic system referred in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council (37) as concerns combined clinical investigations of devices with a clinical trial under that Regulation.

3. 第 1 段（c）点所述信息，仅成员国和委员会。该段其他点中所述的信息方可向公众公开，除非所有或部分信息对信息保密以下述任何理由作为正当理由： The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

(a) 按照欧洲委员会第 45/2001 号法规保护个人数据； protection of personal data in accordance with Regulation (EC) No 45/2001;

(b) 保护商业机密信息，尤其是研究者的资料，特别是考虑到对器械进行符合性评估的状态，除非公开信息中有涉及公共利益的压倒性内容， protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

(c) 有效监督有关成员国进行临床研究的情况； effective supervision of the conduct of the clinical investigation by the Member State(s) concerned.

4. 受试者个人资料不得公开。 No personal data of subjects shall be publicly available.

5. 第 1 段中所述的电子系统使用者界面应具有欧盟所有官方语言的版本。 The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

（1） 欧洲议会及委员会 2014 年 4 月 16 日签发的关于用于人医疗产品临床试验并废除第 2001/20/EC 号指令的第 536/2014 号法规（OJ L 158, 27.5.2014, p. 1）

第 74 条

携带 **CE** 标识的器械的临床研究

Clinical investigations regarding devices bearing the CE marking

1. 若在其预期范围内准备进行临床研究以进一步评估，根据第 20（1）条已携带 CE 标识并符合相关符合性评估流程（以下称为“ PMCF 研究 ”）所述预期目的器械时，若在器械正常使用条件下研究会为受试者引入额外创伤或复杂手术且这些额外程序具有侵入性且难以承受，则申办方应通过第 73 条所述的电子系统在其开始前至少 30 天通知相关成员国。申办方应附上附录 XV 第 II 章所述文件作为公告的一部分。第 62（4）条（ b）至（ k）和（m）点、第 75 条、第 76 条、第 77 条和第 80（5）条及附录 XV 有关规定均适用 PMCF 研究。

Where a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), (‘PMCF investigation’), and where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor shall notify the Member States concerned at least 30 days prior to its commencement by means of the electronic system referred to in Article 73. The sponsor shall include the documentation referred to in Chapter II of Annex XV as part of the notification. Points (b) to (k) and (m) of Article 62(4), Article 75, Article 76, Article 77, Article 80(5) and the relevant provisions of Annex XV shall apply to PMCF investigations.

2. 若根据第 20（1）条、第 62 条至第 81 条规定进行临床研究是为评估超出其预期目的范围，则已携带 CE 标识的器械应适用。

Where a clinical investigation is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with Article 20(1), Articles 62 to 81 shall apply.

第 75 条

临床研究的实质性修改

Substantial modifications to clinical investigations

1. 若申办方拟对临床研究提出可能对受试者安全性、健康或权利产生重大影响的修改，或对研究产生的临床数据的稳健性或可靠性进行修改，则其应在一周内通过第 73 条所述的电子系统，通知相关 （正在进行临床研究或将急性临床研究）成员国有关这些修改的理由及性质。申办方应加入附录 XV 第 II 章所述相关文件的更新版本作为该公告的一部分。相关文件修改更改应清晰可辨。If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, it shall notify, within one week, by means of the electronic system referred to in Article 73 the Member State(s) in which the clinical investigation is being or is to be conducted of the reasons for and the nature of those modifications. The sponsor shall include an updated version of the relevant documentation referred to in Chapter II of Annex XV as part of the notification. Changes to the relevant documentation shall be clearly identifiable.

2. 成员国应根据第 71 条规定程序评估临床研究的任何实质性修改。The Member State shall assess any substantial modification to the clinical investigation in accordance with the procedure laid down in Article 71.

3. 申办方可在该段所述的公告后最早 38 天实施第 1 段所述修改，除非：The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after the notification referred to in that paragraph, unless:

（a）正在进行临床研究或将进行临床研究的成员国已根据第 71（4）条规定或者公共卫生注意事项、公共政策的受试者和使用者安全或健康通知申办方拒绝该修改，或 the Member State in which the clinical

investigation is being or is to be conducted has notified the sponsor of its refusal based on the grounds referred to in Article 71(4) or on considerations of public health, subject and user safety or health, of public policy, or

（b）成员国伦理委员会根据国家法律发布对整个成员国有效的有关对临床研究实质性修改的否定意见。 an ethics committee in that Member State has issued a negative opinion in relation to the substantial modification to the clinical investigation, which, in accordance with national law, is valid for that entire Member State.

4. 为咨询有关专家， 有关成员国可将第 3 段规定的期限额外延长 7 天。The Member State(s) concerned may extend the period referred to in paragraph 3 by a further seven days, for the purpose of consulting with experts.

第 76 条

成员国纠正措施以及成员国之间的信息交流

Corrective measures to be taken by Member States and information exchange between Member States

1. 若正在进行临床研究或将进行临床研究的成员国有理由认为出现了未满足本法规的情况，其至少应在其领土范围内采取以下任何措施： Where a Member State in which a clinical investigation is being or is to be conducted has grounds for considering that the requirements set out in this Regulation are not met, it may take at least any of the following measures on its territory:

(a) 撤销临床研究授权； revoke the authorisation for the clinical investigation;

(b) 暂停或终止临床研究； suspend or terminate the clinical investigation;

(c) 要求申办方修改临床研究所有方面。 require the sponsor to modify any aspect of the clinical investigation.

2. 有关成员国采取第 1 段所述的任何措施之前，除非需要立即采取行动，其应征询申办方或其研究员或两者的意见。应在七日内给出意见。 Before the Member State concerned takes any of the measures referred to in paragraph 1 it shall, except where immediate action is required, ask the sponsor or the investigator or both for their opinion. That opinion shall be delivered within seven days.

3. 若成员国采取了本条第 1 段所述措施，或拒绝临床研究，或已收到申办方基于安全理由提前终止临床研究的通知，则该成员国应通过第 73 条所述的电子系统将相关决议及其理由通知所有成员国和委员会。 Where a Member State has taken a measure referred to in paragraph 1 of this Article or has refused a clinical investigation, or has been notified by the sponsor of the early termination of a clinical investigation on safety grounds, that Member State shall communicate the corresponding decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 73.

4. 如申办方在成员国做出决议之前撤回申请，则应使用第 73 条所述的电子系统通知所有成员国和委员会。 Where an application is withdrawn by the sponsor prior to a decision by a Member State, that information shall be made available through the electronic system referred to in Article 73 to all Member States and the Commission.

第 77 条

在临床研究结束、暂停或提前终止时由申办方提供的信息

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

1. 若申办方临时暂停或提前终止临床研究，则其应在 15 天内通过第 73 条所述的电子系统通知正在进行临床研究或将进行临床研究的成员国临时暂停或提前终止的理由。若申办方临时暂停或提前终止临床研究，则其应在 24

小时内通知正在进行临床研究或将进行临床研究的成员国。 If the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, it shall inform within 15 days the Member State in which that clinical investigation has been temporarily halted or terminated early, through the electronic system referred to in Article 73, of the temporary halt or early termination, providing a justification. In the event that the sponsor has temporarily halted or terminated early the clinical investigation on safety grounds, it shall inform all Member States in which that clinical investigation is being conducted thereof within 24 hours.

2. 临床研究的结束应视为与最后一次研究的最后一次访问一致，除非另一个时间点在临床研究计划中列出。 The end of a clinical investigation shall be deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the clinical investigation plan.

3. 申办方应通知各正在开展临床研究的各成员国，该成员国已结束临床研究。该通知应在该成员国临床研究结束后 15 天内给出。 The sponsor shall notify each Member State in which a clinical investigation was being conducted of the end of that clinical investigation in that Member State. That notification shall be made within 15 days of the end of the clinical investigation in relation to that Member State.

4. 若在多个成员国进行该研究，则申办方应通知所有进行临床研究的成员国已全面结束临床研究。该通知应在临床研究全面结束后 15 天内提出。 If an investigation is conducted in more than one Member State, the sponsor shall notify all Member States in which that clinical investigation was conducted of the end of the clinical investigation in all Member States. That notification shall be made within 15 days of that end of the clinical investigation.

5. 无论临床研究结果如何，在临床研究结束后一年内或在提前终止或暂停的三个月内，申办方应向进行附录 XV 第 I 章第 2.8 节和第 III 章第 7 节所述的临床研究的成员国提交临床研究报告。 Irrespective of the outcome of the clinical investigation, within one year of the end of the clinical investigation or within three months of the early termination or temporary halt, the sponsor shall submit to the Member States in which a clinical investigation was conducted a clinical investigation report as referred to in Section 2.8 of Chapter I and Section 7 of Chapter III of Annex XV.

应提交临床研究报告总结，且措词易于预期使用者理解。报告及总结均应由申办方使用第 73 条所述的电子系统提交。 The clinical investigation report shall be accompanied by a summary presented in terms that are easily understandable to the intended user. Both the report and summary shall be submitted by the sponsor by means of the electronic system referred to in Article 73.

若因科学原因不能在研究完成后一年内提交临床研究报告，须尽快提交。在此种情况下，附录 XV 第 II 章第 3 节中所述的临床研究计划应规定何时提交临床研究结果及其理由。 Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it shall be submitted as soon as it is available. In such case, the clinical investigation plan referred to in Section 3 of Chapter II of Annex XV shall specify when the results of the clinical investigation are going to be available, together with a justification.

6. 委员会应发布关于临床研究报告的总结和概要的指南。 The Commission shall issue guidelines regarding the content and structure of the summary of the clinical investigation report.

此外，委员会可发布设计和共享原始数据及申办方决定是否自愿共享原始数据的准则。这些指南可作为基础，并在可能的情况下适应于临床研究领域共享原始数据的现有准则。 In addition, the Commission may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis. Those guidelines may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical investigations.

7. 本条第 5 段规定的临床研究总结和报告应通过第 73 条所述的电子系统，最迟在器械根据第 29 条规定注册并在投放市场前允许公开访问。在提前终止或暂时停止的情况下，总结和报告提交后，应能立即公开访问。 The summary and the clinical investigation report referred to in paragraph 5 of this Article shall become publicly accessible through the electronic system referred to in Article 73, at the latest when the device is registered in accordance with

Article 29 and before it is placed on the market. In cases of early termination or temporary halt, the summary and the report shall become publicly accessible immediately after submission.

若根据第 29 条, 器械未在总结和报告根据第 5 段规定输入电子系统后的一年内注册, 则应在该时间点公开访问。

If the device is not registered in accordance with Article 29 within one year of the summary and the report having been entered into the electronic system pursuant to paragraph 5 of this Article, they shall become publicly accessible at that point in time.

第 78 条

临床研究的协调评估流程

Coordinated assessment procedure for clinical investigations

1. 在一个以上成员国中进行临床研究的申办方就第 70 条目的，通过第 73 条所述的电子系统提交一份单一申请，且一经收到该申请即以电子方式传送至进行临床研究的成员国。 By means of the electronic system referred to in Article 73, the sponsor of a clinical investigation to be conducted in more than one Member State may submit, for the purpose of Article 70, a single application that, upon receipt, is transmitted electronically to all Member States in which the clinical investigation is to be conducted.

2. 进行第 1 段所指单项申请时，申办方应提议将进行临床研究的成员国之一的身份担任协调成员国。将进行临床研究的成员国应在提交申请后六天内商定任命其中一个成员国担任协调成员国的角色。若各有关成员国未商定协调成员国，则由申办方提议的成员国担任。 The sponsor shall propose in the single application referred to in paragraph 1 that one of the Member States in which the clinical investigation is to be conducted acts as coordinating Member State. The Member States in which the clinical investigation is to be conducted shall, within six days of submission of the application, agree on one of them taking the role of the coordinating Member State. If they do not agree on a coordinating Member State, the coordinating Member State proposed by the sponsor shall assume that role.

3. 在第 2 段所述的协调成员国指导下，相关成员国应协调其对申请的评估，尤其是根据附录 XV 第 II 章提交的文件，应分别由各有关成员国评估。 Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation referred to in Chapter II of Annex XV.

   但附件 XV 第 II 章第 1.13、第 3.1.3、第 4.2、第 4.3 和第 4.4 节中所述的文档完整性应根据第 70（1）条至第（5）条规定由有关成员国分别评估。 However, the completeness of the documentation referred to in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV shall be assessed separately by each Member State concerned in accordance with Article 70(1) to (5).

4. 对于未在第 3 段第二子段中所述的文件， 协调成员国应： With regard to documentation other than that referred to in the second subparagraph of paragraph 3, the coordinating Member State shall:

   (a) 在收到单项申请 6 天内通知申办方其为协调成员国（通知日期）；within six days of receipt of the single application, notify the sponsor that it is the coordinating Member State (‘notification date’);

   (b) 为确认申请，需要考虑到任何相关国在通知日期 7 天内提交的任何考虑事项； for the purpose of the validation of the application, take into account any considerations submitted within seven days of the notification date by any Member State concerned;

   (c) 在通知日期后 10 天内，评估临床研究是否属于本法规范围及其申请是否完整并应相应通知申办方。 第 70(1)和（3）至 (5)条规定应适用于该评估协调成员国。 within 10 days of the notification date, assess whether the clinical investigation falls within the scope of this Regulation and whether the application is complete, and shall notify the sponsor accordingly. Article 70(1) and (3) to (5) shall apply to the coordinating Member State in relation to that assessment;

   (d) 在评估报告草案中给出其评估结果，并在有关成员国有效期限 26 日内进行提交。直至有效期限第 38 日，其他有关成员国可将评估报告草案和基本申请的相关意见和建议提交至协调成员国，且应在最终评估报告最后定稿时充分考虑协调成员国， 并在申办方和有关成员国和其他相关成员国有效期限 45 日内进行提交。 establish the results of its assessment in a draft assessment report to be transmitted within 26 days of the validation date to the Member States concerned. By day 38 after the validation date, the other Member States concerned shall transmit their comments and proposals on the draft assessment report

and the underlying application to the coordinating Member State which shall take due account of those comments and proposals in its finalisation of the final assessment report, to be transmitted within 45 days of the validation date to the sponsor and the other Member States concerned.

其他相关成员国在根据第 70(7)条决定是否同意申办方申请时应考虑最终评估报告。 The final assessment report shall be taken into account by all Member States concerned when deciding on the sponsor's application in accordance with Article 70(7).

5. 有关第 3 段第二子段中的文件评估，各相关成员国可一次性请求申办方提供补充资料。申办方应在有关成员国规定的期限内提交要求的额外信息，该日期不得超过收到请求日算起的 12 天。第 4 段（d）点规定的最后期限到期应自请求日起至收到补充资料时止。 As regards the assessment of the documentation referred to in the second subparagraph of paragraph 3, each Member State concerned may request, on a single occasion, additional information from the sponsor. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed 12 days from the receipt of the request. The expiry of the last deadline pursuant to point (d) of paragraph 4 shall be suspended from the date of the request until such time as the additional information has been received.

6. 对于 IIb 和 III 类器械，协调成员国还可将第 4 段所述期限再延长 50 天，以便与专家进行商议。 For class IIb and class III devices, the coordinating Member State may also extend the periods referred to in paragraph 4 by a further 50 days, for the purpose of consulting with experts.

7. 委员会可通过实施细则，规定由协调成员国指导的协调评估流程和时间表，且相关成员国在决定是是否申办方申请时应考虑这些流程和时间表。此种实施细则还可包括根据本条第 12 段进行重大修改情况下的协调评估流程，以及根据第 80(4)条报告不良事件或在药械组合产品的临床研究，其中药品是根据欧盟第 536/2014 号法规进行临床试验的并行协调评估。应按照第 114(3)条中述及的审查规程通过这些实施细则。 The Commission may, by means of implementing acts, further specify the procedures and timescales for coordinated assessments to be taken into account by Member States concerned when deciding on the sponsor's application. Such implementing acts may also set out the procedures and timescales for coordinated assessment in the case of substantial modifications pursuant to paragraph 12 of this Article, in the case of reporting of adverse events pursuant to Article 80(4) and in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) No 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3)

8. 若协调评估成员成员国商定接受或在符合特定条件情况下接受该临床研究，则应将该商定视为所有相关成员国的最终结论。 Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the conduct of the clinical investigation is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member States concerned.

尽管第一子段有所规定，有关成员国可对协调成员国在协调评估部分的结论提出异议，但仅限于以下理由：

Notwithstanding the first subparagraph, a Member State concerned may only disagree with the conclusion of the coordinating Member State concerning the area of coordinated assessment on the following grounds:

(a) 当其认为参与临床研究会导致受试者接受比相关成员国正常临床实践更差的治疗时； when it considers that participation in the clinical investigation would lead to a subject receiving treatment inferior to that received in normal clinical practice in that Member State concerned;

(b) 违反国家法律；或 infringement of national law; or

(c) 关于根据第 4 段（b）点提交的受试者安全和数据可靠性和稳健性的考虑。 considerations as regards subject safety and data reliability and robustness submitted under point (b) of paragraph 4.

在本段第二子段基础上， 凡有关成员国对结论持有异议的，应通过第 73 条所述的电子系统， 向委员会、所有其他有关成员国及申办方传达其异议及详细理由。 Where one of the Member States concerned disagrees with the

conclusion on the basis of the second subparagraph of this paragraph, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 73, to the Commission, to all other Member States concerned and to the sponsor.

9. 协调成员国关于协调评估领域的结论为临床研究不使用，则该结论应视为所有有关成员国的结论。 Where the conclusion of the coordinating Member State concerning the area of coordinated assessment is that the clinical investigation is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.

10 若相关成员国不同意协调成员国对第 8 段第二子段所述理由的商定，或若其有充分理由认为未遵守附录 XV 第 II 章第 1.13、3.1.3、4.2、4.3 和 4.4 节规定，或道德委员会发布了根据国家法律对整个成员国均有效的有关临床研究否定意见，则相关成员国应拒绝授权进行临床研究。成员国应提供有关此类拒绝申请的上诉程序。 A Member State concerned shall refuse to authorise a clinical investigation if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 8, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV are not complied with, or where an ethics committee has issued a negative opinion in relation to that clinical investigation, which is valid, in accordance with national law, for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.

11 各相关成员国应通过第 73 条所述的电子系统通知申办方临床研究是否获得授权、是否获得条件授权或是否拒绝授权。根据第 4 段（b）规定，应在协调成员国最后评估报告传送后的五天内通过单一决议发出通知。受条件所限的临床研究授权仅限于在授权时无法满足条件的情况。 Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 73 as to whether the clinical investigation is authorised, whether it is authorised subject to conditions, or whether authorisation has been refused. Notification shall be done by way of one single decision within five days of the transmission, pursuant to point (d) of paragraph 4, by the coordinating Member State of the final assessment report. Where an authorisation of a clinical investigation is subject to conditions, those conditions may only be such that, by their nature, they cannot be fulfilled at the time of that authorisation.

12. 第 75 条所述的实质修改应通过第 73 条所述的电子系统通知相关成员国。 除非对附录 XV 第 II 章第 1.13.、3.1.3.、4.2.、4.3.和 4.4.节作了重大修改，否则关于第本条 8 段第二子段所述是否有分歧理由的任何评估应在协调成员国的指导下进行，由各有关成员国自行评估。 Any substantial modifications as referred to in Article 75 shall be notified to the Member States concerned by means of the electronic system referred to in Article 73. Any assessment as to whether there are grounds for disagreement as referred to in the second subparagraph of paragraph 8 of this Article shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning Sections 1.13, 3.1.3, 4.2, 4.3 and 4.4 of Chapter II of Annex XV, which shall be assessed separately by each Member State concerned.

13. 委员会应在协调成员国完成本章规定的任务时向其提供行政支持。 The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks under this Chapter.

14. 本条规定的程序应在 2027 年 5 月 27 日之前，仅适用于已同意实施临床研究的成员国。在 2027 年 5 月 27 日之后，所有成员国均须申请该程序。 The procedure set out in this Article shall, until 27 May 2027, be applied only by those of the Member States in which the clinical investigation is to be conducted which have agreed to apply it. After 27 May 2027, all Member States shall be required to apply that procedure.

第 79 条

审查协调评估流程 **Review of coordinated assessment procedure**

在 2026 年 5 月 27 日前，委员会应向欧洲议会和理事会提交一份关于适用第 78 条所获经验的报告，并在必要时提出对第 78（14）和第 123（3）条（ h）点的审查。 By 27 May 2026, the Commission shall submit to the European Parliament and to the Council a report on experience gained from the application of Article 78 and, if necessary, propose a review of

Article 78(14) and point (h) of Article 123(3).

第 80 条

记录并报告临床研究期间发生的不良事件

Recording and reporting of adverse events that occur during clinical investigations

1. 申办方应充分记录以下所有情况： The sponsor shall fully record all of the following:

(a) 在临床研究中确定, 对根据临床研究计划的临床研究结果的评估至关重要的不良事件； any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation;

(b) 任何严重不良事件； any serious adverse event;

(c) 当未能采取适当措施、 没有发生干预或情况不利时, 可能导致严重不良事件的任何器械缺陷； any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(d) 有关（a）至（c）所所述任何事件的新发现。 any new findings in relation to any event referred to in points (a) to (c).

2. 申办方应通过第 73 条所述的电子系统，向所有进行临床研究的成员国报告以下信息，不得有任何延迟： The sponsor shall report, without delay to all Member States in which the clinical investigation is being conducted, all of the following by means of the electronic system referred to in Article 73:

(a) 与研究器械、比对产品或研究流程有因果关系的任何严重不良事件，或者这种因果关系是合理的； any serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;

(b) 当未能采取适当措施、 没有发生干预或情况不利时, 可能导致严重不良事件任何的器械缺陷； any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;

(c) 有关（a）和（b）所所述任何事件的新发现。 any new findings in relation to any event referred to in points (a) and (b).

报告的时间段应考虑事件的严重性。必要时，为确保及时报告，申办方可先提交初步的不完整报告，后续提交完整报告。 The period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

根据进行临床研究的成员国要求，申办方应提供第 1 段中所述的所有信息。 Upon request by any Member State in which the clinical investigation is being conducted, the sponsor shall provide all information referred to in paragraph 1.

3. 申办方还应向有关成员国报告发生在第三国本条第 2 段所述的任何事件, 其中临床研究通过第 73 条所述电子系统，适用于本法规所含临床研究的同一临床研究计划进行。 The sponsor shall also report to the Member States in which the clinical investigation is being conducted any event referred to in paragraph 2 of this Article that occurred in third countries in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Regulation by means of the electronic system referred to in Article 73.

4. 对于申办方使用第 78 条所述的单一申请的临床研究，申办方应通过第 73 条所述的电子系统报告本条第 2 段所述的任何事件。 一旦收到后, 本报告应以电子方式传送给所有相关成员国。 In the case of a clinical investigation for which the sponsor has used the single application referred to in Article 78, the sponsor shall report any event as referred to in paragraph 2 of this Article by means of the electronic system referred to in Article 73. Upon receipt, this report shall be transmitted electronically to all Member States in which the clinical

investigation is being conducted.

在第 78(2)条所述的协调成员国的指导下，成员国应协调对严重不良事件和器械缺陷的评估，以确定是否需要修改、暂停、或终止临床研究或是否撤销该临床研究授权。 Under the direction of the coordinating Member State referred to in Article 78(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether to modify, suspend or terminate the clinical investigation or whether to revoke the authorisation for that clinical investigation.

本段不得影响其他成员国为确保保护公共卫生和患者安全，根据本法规自己执行评估和采取措施的权利。并应随时通知协调成员国和委员会任何此类评估的结果以及采取的任何此类措施。 This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. 在第 74(1)条所述的 PMCF 的情况下，应适用第 87 至 90 条所列明的关于警戒的规定且根据第 91 条采用的法案因代替本条。 In the case of PMCF investigations referred to in Article 74(1), the provisions on vigilance laid down in Articles 87 to 90 and in the acts adopted pursuant to Article 91 shall apply instead of this Article.

6. 尽管有第 5 段规定，若严重不良事件与前述研究流程建立了因果关系，本条将适用。 Notwithstanding paragraph 5, this Article shall apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.

第 81 条

实施细则 **Implementing acts**

委员会可通过实施细则，采取实施本章所需的详细安排和程序，涉及以下方面： The Commission may, by means of implementing acts, establish the detailed arrangements and procedural aspects necessary for the implementation of this Chapter as regards the following:

(a) 协调电子表格，用于第 70 和 78 条所述的临床研究及其评估申请，并考虑到特定类别或器械组； harmonised electronic forms for the application for clinical investigations and their assessment as referred to in Articles 70 and 78, taking into account specific categories or groups of devices;

(b) 第 73 条所所述电子系统的运作； the functioning of the electronic system referred to in Article 73;

(c) 第 74(1)条所述的 PMCF 研究通知的协调电子表格，以及第 75 条所述的实质性修改； harmonised electronic forms for the notification of PMCF investigations as referred to in Article 74(1), and of substantial modifications as referred to in Article 75;

(d) 第 76 条所述成员国之间的信息交流； the exchange of information between Member States as referred to in Article 76;

(e) 用于报告第 80 条所述严重不良事件和器械缺陷的协调电子表格； harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 80;

(f) 考虑到第 80 条所述报告事件的严重性，用于报告严重不良事件和器械缺陷的时间表； the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 80;

(g) 需要有关临床证据/数据要求的统一应用，以证明符合附录 I 所规定的通用安全与性能要求。 uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I

应按照第 114(3) 条中述及的审查规程通过这些在第 1 段中实施细则。 The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 82 条

关于其他临床研究的要求 **Requirements regarding other clinical investigations**

1. 未按照第 62（1）条任何目的进行的临床研究，应符合本法规第 62（2）和（ 3）条，第 62（4）条（ b）、(c)、(d)、(f)、（h）和（l）点和和第 62（6）条。Clinical investigations, not performed pursuant to any of the purposes listed in Article 62(1), shall comply with the provisions of Article 62 (2) and (3), points (b), (c), (d), (f), (h), and (l) of Article 62(4) and Article 62(6).

2. 出于保护受试者的权利、 安全、尊严和福祉以及根据第 62(1)条所列任何目的未进行的临床研究的科学和伦理完整性，各成员国应明确任何附加要求酌情为各有关成员国进行此类研究。 In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in Article 62(1), each Member State shall define any additional requirements for such investigations, as appropriate for each Member State concerned.

第 **VII** 章

上市后监管、警戒和市场监管

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

第 **1** 节

上市后监管

Post-market surveillance

第 83 条

制造商的上市后监管体系

Post-market surveillance system of the manufacturer

1. 根据第 10(9)条的规定，对于与风险等级相称并且适合于该器械类型的任何器械，制造商应计划、建立、记录、实施、维护和更新上市后的监管体系，该系统应属于制造商质量管理体系的组成部分。 or each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).

2. 上市后的监管体系应适于积极和系统地收集、记录并分析器械在其整个生命周期内的质量、性能和安全相关数据，以得出必要的结论， 并确定、 实施和监测任何预防及纠正措施。 The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. 由制造商的上市后监管体系收集的数据应特别用于： Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

   (a) 更新收益风险测定改善附录 I 第 I 章中所述的风险管理； to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

   (b) 更新设计和生产信息、使用和标签说明 to update the design and manufacturing information, the instructions for use and the labelling;

   (c) 更新临床评价； to update the clinical evaluation;

(d) 更新第 32 条所述的安全和临床性能总结文件； to update the summary of safety and clinical performance referred to in Article 32;

(e) 用于确定预防、 纠正或现场安全纠正措施的需要； for the identification of needs for preventive, corrective or field safety corrective action;

(f) 用于确定提高器械的可用性、 性能和安全性的可能性； for the identification of options to improve the usability, performance and safety of the device;

(g) 当与之相关时， 协助其他器械的上市后监管。 when relevant, to contribute to the post-market surveillance of other devices; and

(h) 根据第 88 条检测并报告趋势。 to detect and report trends in accordance with Article 88.

技术文件应进行相应的更新。 The technical documentation shall be updated accordingly.

4. 若在上市后监管的过程中确定需要采取预防或纠正措施或两者，制造商应采取适当的措施，并通知相关主管机构和公告机构 （如适用）。当发现严重事件或实施现场安全纠正措施时， 应按照第 87 条进行报告。 If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87.

第 84 条

上市后监管计划 **Post-market surveillance plan**

第 83 条所述的上市后监管体系应以上市后监管计划为基础，其要求载于附录 III 的第 1.1 节。对于非定制器械，上市后监管计划应是附录 II 中规定的技术文件的一部分。 The post-market surveillance system referred to in Article 83 shall be based on a post-market surveillance plan, the requirements for which are set out in Section 1.1 of Annex III. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation specified in Annex II.

第 85 条

上市后监管报告 **Post-market surveillance report**

I 类器械制造商应编制一份上市后监管报告，总结根据从 84 条所述的上市后监管计划收集的数据的分析结果和结论，以及采取的任何预防和纠正措施的理由和说明。 必要时应更新报告， 并应主管机构的要求提供。 Manufacturers of class I devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

第 86 条

定期安全性更新报告 **Periodic safety update report**

1. IIa、IIb 和 III 类器械制造商应针对各器械或类别或器械组编制定期安全性更新报告（ PSUR），总结根据从第 84 条所述的上市后监管计划收集的数据分析结果和结论，并对采取的任何预防和纠正措施提供理由和说明。在该器械的整个生命周期内， PSUR 应列出： Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic saf ety update report (‘PSUR’) for each device and where relevant for each category or group of

devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

(a) 收益风险测定的结论； the conclusions of the benefit-risk determination;

(b) PMCF 的主要问题；和 the main findings of the PMCF; and

(c) 器械的销售量和使用涉及器械的群体大小和其他特征评估, 以及实际可行时器械的使用频率。 the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

IIb 和 III 类器械的制造商应至少每年更新 PSUR。除非是定制器械, 否则 PSUR 应作为附录 II 和 III 规定的技术文件的一部分。 Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

IIa 类器械制造商应在必要时至少每两年更新 PSUR。除非是定制器械，否则 PSUR 应作为附录 II 和 III 规定的技术文件的一部分。 Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

对于定制器械, PSUR 应作为附录 XII 第 2 节所述文件的一部分。 For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII.

2. III 类器械或可植入器械的制造商应按照第 52 条的规定, 通过第 92 条所述的电子系统向参与符合性评估的公告机构提交 PSUR。公告机构应审查该 PSUR，并将其评估添加到电子系统中，包括采取任何措施的细节。此外, 此类 PSUR 和公告机构的评估应通过电子系统提供给主管机构。 For class III devices or implantable devices, manufacturers shall submit PSURs by means of the electronic system referred to in Article 92 to the notified body involved in the conformity assessment in accordance with Article 52. The notified body shall review the report and add its evaluation to that electronic system with details of any action taken. Such PSURs and the evaluation by the notified body shall be made available to competent authorities through that electronic system.

3. 对于第 2 段所述以外的器械制造商应向参与符合性评估的公告机构提交 PSUR，并应要求向主管机构提供报告。 For devices other than those referred to in paragraph 2, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

第 **2** 节

警戒

第 87 条

报告严重事件和现场安全纠正措施

Reporting of serious incidents and field safety corrective actions

1. 在欧盟市场上提供不同于研究器械的器械制造商，应按照第 92（5）和（ 7）条向相关主管机构报告以下内容：
Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7), the following:

(a) 任何涉及在欧盟市场上销售器械的严重事件，但不包括产品信息中清楚地记录并在技术文件中量化的预期副作用外， 并根据第 88 条接受趋势报告； any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;

(b) 任何有关欧盟市场上销售器械的现场安全纠正措施，若现场安全纠正措施的原因并不仅限于在第三类国家销售的器械， 则包括第三国对在欧盟市场上合法提供的器械所采取的任何现场安全纠正措施。 any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

应通过第 92 条中所述的电子系统提交第一子段中所述的报告。 The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.

2. 作为一般规则，第 1 段中所述报告的时间段应考虑到严重事件的严重性。 As a general rule, the period for the reporting referred to in paragraph 1 shall take account of the severity of the serious incident.

3. 制造商应在制造商与其器械建立了事件之间因果关系后或者发现这种因果关系合理时， 立即报告第 1 段（a）点中所述的任何严重事件，这一时限不迟于其意识到严重事件后的 15 天。 Manufacturers shall report any serious incident as referred to in point (a) of paragraph 1 immediately after they have established the causal relationship between that incident and their device or that such causal relationship is reasonably possible and not later than 15 days after they become aware of the incident.

4. 尽管有第 3 段的规定，若出现严重的公共卫生事件，则应立即提供第 1 段中所述的报告，且不迟于制造商察觉到此威胁后 2 天。 Notwithstanding paragraph 3, in the event of a serious public health threat the report referred to in paragraph 1 shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

5. 尽管有第 3 段的规定，若出现人员死亡或健康状况意外严重恶化，该报告应在制造商确认或可疑器械与严重事件之间的因果关系后立即提供， 且不迟于制造商察觉到该严重事件之日后 10 天。 Notwithstanding paragraph 3, in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

6. 必要时，为确保及时报告，制造商可先提交初步的不完整报告，后续提交完整报告。 Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

7. 若在察觉到潜在可报告事件之后，制造商仍然存在不确定事件是否可报告，制造商应根据第 2 至 5 段规定所需的时间框架内提交报告。 If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain

about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 2 to 5.

8. 除非紧急情况下制造商需要立即采取现场安全纠正措施, 否则制造商应在报告第 1 段（b）点所述的现场安全纠正措施之后, 采取现场安全纠正措施。 Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field safety corrective action referred to in point (b) of paragraph 1 in advance of the field safety corrective action being undertaken.

9. 对于使用相同的器械或器械类型发生的类似严重事件, 并且已经确定了根本原因或采取了现场安全纠正措施后, 或者事故是常见且记录完好的, 制造商可提供定期总结报告, 而非个别严重事件, 条件是第 89（9）条所述的协调主管机构与第 92（8）条（a）点所述主管机构咨询, 同制造商商定定期总结报告的格式、内容和频率。若第 92（8）条（a）和（b）点所述单一主管机构, 则制造商可根据与主管机构的协议提供定期总结报告。 For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 89(9), in consultation with the competent authorities referred to in point (a) of Article 92(8), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. Where a single competent authority is referred to in points (a) and (b) of Article 92(8), the manufacturer may provide periodic summary reports following agreement with that competent authority.

10. 成员国应采取适当措施, 例如有针对性的宣传活动, 以鼓励并使得医护专业人员、使用者和患者能够向其主管机构报告第 1 段（a）点所述的可疑严重事件。 The Member States shall take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities suspected serious incidents referred to in point (a) of paragraph 1.

主管机构应记录其在国家层面集中从健康护理人员、使用者和患者收到的报告。 The competent authorities shall record centrally at national level reports they receive from healthcare professionals, users and patients.

11. 若成员国的主管机构获得此类报告, 则它应采取必要步骤, 确保立即向相关器械制造商通报从健康护理人员、使用者和患者收到第 1 段（a）点中所述的可疑严重事件。 Where a competent authority of a Member State obtains such reports on suspected serious incidents referred to in point (a) of paragraph 1 from healthcare professionals, users or patients, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

若有关器械的制造商认为该事件为严重事件, 其应根据本条第 1 段至第 5 段有关严重事件的规定向发生严重事件的成员国主管机构提交关于严重事件的报告, 并应适当跟踪并根据第 89 条行动；若制造商认为事故非严重事件或属于预期不良副作用, 则应根据第 88 条由趋势报告涵盖, 并提供解释性说明。 Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs 1 to 5 of this Article on that serious incident to the competent authority of the Member State in which that serious incident occurred and shall take the appropriate follow-up action in accordance with Article 89.

若主管机构不同意解释性说明的结论, 可能要求制造商根据本条第 1 至 5 段提供报告, 确保根据第 89 条采取适当的跟踪措施。 Where the manufacturer of the device concerned considers that the incident is not a serious incident or is an expected undesirable side-effect, which will be covered by trend reporting in accordance with Article 88, it shall provide an explanatory statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with paragraphs 1 to 5 of this Article and require it to ensure that appropriate follow-up action is taken in accordance with Article 89.

第 88 条

趋势报告

Trend reporting

1. 制造商应通过第 92 条所述的电子系统报告非严重事件或预期不良副作用事件在统计方面显著增加的频率或严重程度，这些事件可能对附录 I 第 1 节和第 5 节中所述的风险 - 收益分析产生重大影响，在衡量预期收益时，事件已经导致或可能导致对患者、使用者或其他人的健康或安全造成不可接受的风险。与技术文件中规定的特定时间段内有关器械或类别或器械组有关的此类事故的预计频率或严重程度以及产品信息。 Manufacturers shall report, by means of the electronic system referred to in Article 92, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

   制造商应明确如何管理这些在第一子段中所述的事故和用于确定这些事故的频率或严重程度，以及观察期间在根据第 84 条的上市后监管计划中的任何在统计方面显著增加的方法。 The manufacturer shall specify how to manage the incidents referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in Article 84.

2. 主管机构可对第 1 段所述的趋势报告自己进行评估，并要求制造商根据本法规定采取适当措施，确保保护公众健康和患者安全。各主管机构应向委员会、其他主管机构以及颁发证书的公告机构，通知此类评估结果和采取的此类措施。 The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. Each competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such assessment and of the adoption of such measures.

第 89 条

严重事件分析和现场安全纠正措施

Analysis of serious incidents and field safety corrective actions

1. 在根据第 87(1) 条报告严重事件后，制造商应立即对相关严重事件和相关器械进行必要的研究。包括对事件和现场安全纠正措施进行风险评估，并酌情考虑本条第 3 段中所列的标准。 Following the reporting of a serious incident pursuant to Article 87(1), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the devices concerned. This shall include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph 3 of this Article as appropriate.

   在将此类措施通知主管机构之前，制造商应在第一子段所述的研究期间与主管机构以及相关的公告机构（适当时）合作，并且不得执行任何涉及更改器械或相关批次样品的研究，因为可能会影响后续对事件原因的评估。 The manufacturer shall co-operate with the competent authorities and where relevant with the notified body concerned during the investigations referred to in the first subparagraph and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the competent authorities of such action.

2. 成员国应采取必要措施，确保任何有关在其境内出现严重事件的信息或在其境内已经或将要采取的现场安全纠正措施，且应根据其所知以及按照第 87 条，在国家层面由其主管机构与制造商（如可能）、相关公告机构（适当时）一起进行集中评估。 Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be

undertaken within their territory, and that is brought to their knowledge in accordance with Article 87 is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

3. 在第 2 段所述的评估范围内，主管机构应评估报告的严重事件，并评估任何相关现场安全纠正措施所产生的风险，同时考虑保护公共卫生和标准，如因果关系、可检测性和复发概率问题、器械的使用频率、直接或间接伤害的发生概率和严重性、器械的临床受益、预期和潜在使用者以及受影响的人群。主管机构同时还应评估制造商设想或采取现场安全纠正措施的适当性，对任何其他纠正措施的需求及其种类，特别应考虑到附录 I 所规定的本质安全原则。 In the context of the evaluation referred to in paragraph 2, the competent authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Annex I.

根据国家主管机构的要求，制造商应提供风险评估所需的所有文件。 Upon request by the national competent authority, manufacturers shall provide all documents necessary for the risk assessment.

4. 主管机构应监控制造商对严重事件的研究。必要时，主管机构可干预制造商的研究或独立进行研究。 The competent authority shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.

5. 制造商应通过第 92 条所所述的电子系统，向主管机构提供陈述其研究结果的最终报告。该报告应列出结论，以及何时应采取纠正措施。 The manufacturer shall provide a final report to the competent authority setting out its findings from the investigation by means of the electronic system referred to in Article 92. The report shall set out conclusions and where relevant indicate corrective actions to be taken.

6. 对于第 1(8) 条第一子段所述器械，若严重事件或现场安全纠正措施可能与一种物质相关，该物质若单独使用，可被视作一种药品，评估主管机构或本条第 9 段所述的协调主管机构（取决于该严重事件或现场安全纠正措施第 52（9）条下物质发布的科学意见）应通知国家主管机构或 EMA 。 In the case of devices referred to in the first subparagraph of Article 1(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the evaluating competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall, inform the national competent authority or the EMA, depending on which issued the scientific opinion on that substance under Article 52(9), of that serious incident or field safety corrective action.

在本法规根据第 1(6)条（ g）涵盖器械的情况下，以及可能与用于生产器械的人体组织或细胞衍生物有关的严重事件或现场安全纠正措施，及器械未能遵守第 1（10）法规的情况下，本条第 9 段所述的主管机构或协调主管机构应通知根据第 52（10）条由公告机构咨询的人体组织和细胞的主管机构。 In the case of devices covered by this Regulation in accordance with point (g) of Article 1(6) and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, and in the case of devices falling under this Regulation pursuant to Article 1(10), the competent authority or the coordinating competent authority referred to in paragraph 9 of this Article shall inform the competent authority for human tissues and cells that was consulted by the notified body in accordance with Article 52(10).

7. 在根据本条第 3 段进行评估后，评估主管机构应通过第 92 条所述的电子系统，立即通知其他主管机构制造商或

施加于其采取或设想的纠正行动，以尽量减少严重事件复发的风险，包括关于潜在事件和评估结果的信息。After carrying out the evaluation in accordance with paragraph 3 of this Article, the evaluating competent authority shall, through the electronic system referred to in Article 92, inform, without delay, the other competent authorities of the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident, including information on the underlying events and the outcome of its assessment.

8. 制造商应使用现场安全通告，及时提请有关器械使用者注意将有关现场安全纠正措施的信息。现场安全通告应使用欧盟官方语言或由使用现场安全纠正措施的成员国确定的语言编辑。除紧急情况外，现场安全通知草案的内容应提交给评估主管机构，或在本条第 9 段所述情况下，协调主管机构允许其提出意见。除非个别成员国有正当理由，否则现场安全通告的内容应在所有成员国中保持一致。The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State in which the field safety corrective action is taken. Except in cases of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in the cases referred to in paragraph 9, to the coordinating competent authority to allow it to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.

现场安全通告应允许正确识别所涉及的器械，尤其是包括相关 UDI 和已公布的正确标识符尤其（包括 SRN），以及执行现场安全纠正措施的制造商，现场安全通告应清晰可见，且不存在风险层面，并且有关器械故障的现场安全纠正措施的原因以及患者、使用者或其他人的相关风险，应清楚标示所有使用者应采取的措施。The field safety notice shall allow the correct identification of the device or devices involved, in particular by including the relevant UDIs, and the correct identification, in particular, by including the SRN, if already issued, of the manufacturer that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

制造商应在第 92 条所述的电子系统中输入现场安全通告，并向公众开放。The manufacturer shall enter the field safety notice in the electronic system referred to in Article 92 through which that notice shall be accessible to the public.

9. 主管机构应积极参与协调流程，在以下情况中协调第 3 段所述的评估： The competent authorities shall actively participate in a procedure in order to coordinate their assessments referred to in paragraph 3 in the following cases:

(a) 若存在特定严重事件或一组相同制造商的同一器械或同一类型器械集中在多个成员国中的严重事件；
where there is concern regarding a particular serious incident or cluster of serious incidents relating to the same device or type of device of the same manufacturer in more than one Member State;

(b) 若制造商在多个成员国提出的现场安全纠正措施中存在问题。where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.

该协调流程应包括以下内容： That coordinated procedure shall cover the following:

- 必要时，根据具体情况委任协调主管机构； designation of a coordinating competent authority on a case by case basis, when required;
- 定义协调评估流程，包括协调机构以及其他主管机构参与的任务和责任。defining the coordinated assessment process, including the tasks and responsibilities of the coordinating competent authority

and the involvement of other competent authorities.

除非主管机构另有协议，否则协调主管机构应属于拥有制造商注册地址的成员国主管机构。 Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the competent authority of the Member State in which the manufacturer has its registered place of business.

协调主管机构应通过第 92 条所所述的电子系统，通知制造商、其他主管机构和委员会，承担协调机构的作用。 The coordinating competent authority shall, through the electronic system referred to in Article 92, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

10. 协调主管机构的指定不得影响其他主管机构为确保保护公共卫生和患者安全，而根据本法规执行评估和采取措施的权利。并应随时通知协调主管机构和委员会任何此类评定的结果以及采取的任何此类措施。 The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.

11. 委员会应在协调主管机构根据本章完成任务时提供行政支持。 The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

第 90 条

警戒数据分析 **Analysis of vigilance data**

委员会应与成员国合作，落实系统和流程，主动监测第 92 条所所述电子系统中可用的数据，以发现数据中可能识别新风险或安全问题的趋势、模式或信号。 The Commission shall, in collaboration with the Member States, put in place systems and processes to actively monitor the data available in the electronic system referred to in Article 92, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

若确定以前未知的风险或确定预期风险频率显著且不利地改变了风险-收益时，由主管机构，或在适当情况下由协调主管机构通知制造商或授权代表，采取必要的纠正措施。 Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, which shall then take the necessary corrective actions.

第 91 条

实施细则 **Implementing acts**

委员会可通过详细安排，并在与 MDCG 咨询后，通过实施第 85 至 90 和 92 条所需的模式和流程方面，包括： The Commission may, by means of implementing acts, and after consultation of the MDCG, adopt the detailed arrangements and procedural aspects necessary for the implementation of Articles 85 to 90 and 92 as regards the following:

(a) 严重事件的类型学和有关特定器械或器械类别或组别的现场安全纠正措施； the typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;

(b) 第 85、86、87、88 和 89 条分别所述的严重事件和现场安全纠正措施的报告、现场安全通知、定期总结报告、上市后监管报告、 PSUR 和趋势报告； the reporting of serious incidents and field safety corrective actions and field safety notices, and the provision of periodic summary reports, post-market surveillance reports, PSURs and trend reports by manufacturers as referred to in Articles 85, 86, 87, 88 and 89 respectively;

(c) 电子和非电子报告的标准结构表格，包括由医疗卫生专业人士、使用者和患者报告可疑严重事件的最小数据集；
standard structured forms for electronic and non-electronic reporting, including a minimum data set for reporting of suspected serious incidents by healthcare professionals, users and patients;

(d) 考虑到第 87 条所述事件的严重性，制造商用于报告现场安全纠正措施、定期总结报告和趋势报告的时间表；
timelines for the reporting of field safety corrective actions, and for the provision by manufacturers of periodic summary reports and trend reports, taking into account the severity of the incident to be reported as referred to in Article 87;

(e) 第 89 条所述主管机构之间交流信息的协调表格；harmonised forms for the exchange of information between competent authorities as referred to in Article 89;

(f) 指定协调主管机构的流程；协调评估过程；协调主管机构以及其他主管机构参与这一进程的任务和责任。
procedures for the designation of a coordinating competent authority; the coordinated evaluation process, including tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.

应按照第 114(3)条中述及的审查规程通过这些在第一段中所述的实施细则。The implementing acts referred to in the first paragraph shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 92 条

有关警戒和上市后监管的电子系统

Electronic system on vigilance and on post-market surveillance

1. 委员会应与成员国合作，设立和管理电子系统整理并处理以下信息：The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:

(a) 制造商关于第 87(1)条和第 89（5）条所述严重事件和现场安全纠正措施的报告；the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 87(1) and Article 89(5);

(b) 第 87(9)条所所述制造商的定期总结报告；the periodic summary reports by manufacturers referred to in Article 87(9);

(c) 制造商关于第 88 条所述趋势的报告；the reports by manufacturers on trends referred to in Article 88;

(d) 第 86 条所述的 PSUR；the PSURs referred to in Article 86;

(e) 第 89(8)条所所述制造商的现场安全通告；the field safety notices by manufacturers referred to in Article 89(8);

(f) 根据第 89(7)和（9）条，成员国主管机构之间以及它们与委员会之间的交换信息。the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 89(7) and (9).

电子系统应包括连接至 UDI 数据库的链接。That electronic system shall include relevant links to the UDI database

2. 通过电子系统整理向成员国主管机构和委员会提供本条第 1 段中所述的信息。根据第 53 条为该器械颁发证书的公告机构开放相关该器械信息。The information referred to in paragraph 1 of this Article shall be made available through the electronic system to the competent authorities of the Member States and to the Commission. The notified bodies shall also have access to that information to the extent that it relates to devices for which they issued a certificate in accordance with Article 53.

3. 委员会应确保医疗卫生专业人士和公众对第 1 段中所述的电子系统具有适当的访问权限。The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system referred to in paragraph 1.

4. 根据委员会与第三类国家或国际组织主管机构之间的约定，委员会可授予此类主管机构或国际组织在适当权限访问第 1 段中所述的电子系统。这些约定应以互惠为基础，提供并适用于欧盟等同的保密和数据保护。 On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the electronic system referred to in paragraph 1 at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. 第 87(1)条（ a）点所所述的严重事件报告应在收到后通过本条第 1 段中所述的电子系统自动传送至发生事件的成员国主管机构。 The reports on serious incidents referred to in point (a) of Article 87(1) shall be automatically transmitted, upon receipt, via the electronic system referred to in paragraph 1 of this Article, to the competent authority of the Member State in which the incident occurred.

6. 第 88（1）条所所述的趋势报告应在收到后通过本条第 1 段中所述的电子系统自动传送至发生事件的成员国主管机构。 The trend reports referred to in Article 88(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the Member State in which the incidents occurred.

7. 第 87(1)条（ b）点所所述的现场安全纠正措施报告应在收到后通过本条第 1 段中所述的电子系统自动传送至下列成员国的主管机构： The reports on field safety corrective actions referred to in point (b) of Article 87(1) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authorities of the following Member States:

   (a) 正在或将要执行现场安全纠正措施的成员国； the Member States in which the field safety corrective action is being or is to be undertaken;

   (b) 拥有制造商注册地址的成员国； the Member State in which the manufacturer has its registered place of business.

8. 第 87(9)条所所述的定期总结报告应在收到后通过本条第 1 段中所述的电子系统自动传送至下列相关主管机构： The periodic summary reports referred to in Article 87(9) shall be automatically transmitted upon receipt via the electronic system referred to in paragraph 1 of this Article to the competent authority of:

   (a) 成员国或根据第 89(9)条参与协调程序并同意定期总结报告的成员国； the Member State or Member States participating in the coordination procedure in accordance with Article 89(9) and which have agreed on the periodic summary report;

   (b) 拥有制造商或其授权代表注册地址的成员国。 the Member State in which the manufacturer has its registered place of business.

9. 本条第 5 至第 8 段所所述的信息应在收到后通过本条第 1 段所述的电子系统自动传送至根据第 56 条为有关器械颁发证书的公告机构。 The information referred to in paragraphs 5 to 8 of this Article shall be automatically transmitted, upon receipt, through the electronic system referred to in paragraph 1 of this Article, to the notified body that issued the certificate for the device in question in accordance with Article 56.

第 **3** 节

市场监管 **Market surveillance**

第 93 条

市场监管活动 Market surveillance activities

1. 主管机构应对器械的符合性特性和性能进行适当检查，包括酌情审查文件以及基于适当样品的物理或实验室检查。主管机构应特别考虑到有关风险评估和风险管理、警戒数据和投诉的既定原则。 The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

2. 主管机构应制定年度监管活动计划，并分配足够数量的胜任人力和物质资源以执行这些活动，同时应根据第 105 条和当地条件，考虑到由 MDCG 制定的欧洲市场监管方案。 The competent authorities shall draw up annual surveillance activity plans and allocate a sufficient number of material and competent human resources in order to carry out those activities taking into account the European market surveillance programme developed by the MDCG pursuant to Article 105 and local circumstances.

3. 为第 1 段规定的义务，主管机构： In order to fulfil the obligations laid down in paragraph 1, the competent authorities:

(a) 可特别要求经济运营商提供开展主管机构活动所必需的文件和信息，并在有充分理由的情况下提供器械的必要样品或免费使用该器械；和 may require economic operators to, inter alia, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

(b) 应对经济运营商以及供应商和/或分包商的营业场所，对专业使用者的设施（必要时）进行通知和不通知的（如有必要）检查。 shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

4. 主管机构应编制监管活动结果的年度总结报告，并通过第 100 条所述的电子系统提供给其他主管机构。 The competent authorities shall prepare an annual summary of the results of their surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 100.

5. 当主管机构认为保护有必要公共卫生的利益时，可没收、销毁器械或以其他方式使得具有不可接受风险或伪造器械停用。 The competent authorities may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where they deem it necessary to do so in the interests of the protection of public health.

6. 在出于第 1 段所述目的进行的每次检查之后，主管机构应起草一份关于遵守本法规适用的法律和技术要求的检查结果的报告。报告应列出所需的任何纠正措施。 Following each inspection carried out for the purposes referred to in paragraph 1, the competent authority shall draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Regulation. The report shall set out any corrective actions needed.

7. 执行检查的主管机构应将本条第 6 段所述的报告的内容传达进行检查的经济运营商。在采用最终报告之前，主管机构应给予受检查的经济运营商提交意见的机会。 并应将第最终检验报告输入第 100 条规定的电子系统。 The competent authority which carried out the inspection shall communicate the content of the report referred to in paragraph 6 of this Article to the economic operator that has been the subject of the inspection. Before adopting the

final report, the competent authority shall give that economic operator the opportunity to submit comments. That final inspection report shall be entered in the electronic system provided for in Article 100.

8. 成员国应审查并评估其市场监管活动的运行情况。此类审查和评估应至少每四年进行一次，其结果应告知其他成员国和委员会。各成员国应通过第 100 条所述电子系统向公众提供结果总结。 The Member States shall review and assess the functioning of their market surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. Each Member State shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 100.

9. 成员国主管机构应协调其市场监管活动，彼此合作，并相互以及与委员会分享其结果，以便在所有成员国提供协调一致的高水平市场监管。 The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States.

在适当情况下，成员国主管机构应达成工作共享、联合市场监管活动和专业化的共识。 Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialization.

10. 若超过一个成员国的当局负责市场监管和外部边界控制，这些当局应通过分享与其作用和职能有关的信息相互合作。 Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.

11. 在适当情况下，成员国主管机构应与第三类主管机构合作，以便交流信息和技术支持，并促进有关市场监管的活动。 Where appropriate, the competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

第 94 条

对涉嫌不可接受风险或其他不合规的器械的评估

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

根据通过警戒或市场监管活动获得的数据或其他信息，成员国的主管机构有理由相信器械： Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or on other information, have reason to believe that a device:

（a）对患者、使用者或其他人的健康或安全，或公共卫生保护的其他方面存在不可接受的风险；或 may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or

（b）否则不符合本法规规定的要求， otherwise does not comply with the requirements laid down in this Regulation,

其应对涉及器械的法规规定的所有相关要求进行评估：由器械呈现的相关风险，或与器械的任何其他不符合项。

相关经济运营商应与主管机构合作。 they shall carry out an evaluation of the device concerned covering all requirements laid down in this Regulation relating to the risk presented by the device, or to any other non-compliance of the device.

第 95 条

对健康和安全带来不可接受风险的器械的处理程序

Procedure for dealing with devices presenting an unacceptable risk to health and safety

1. 当根据第 94 条执行评估后， 倘若主管机构发现该器械可能对患者、 使用者或其他人的健康和安全、 或对保障公众健康的其他方面带来不可接受的风险，则主管机构应符合本法规相关器械所带来风险要求同时与风险性质相称，立即要求相关器械的制造商、其授权代表和其他所有相关经济运营商采取一切适当且合理的纠正措施，以限制该器械在市场上的流通，或使该器械的流通遵守特定要求，或将该器械撤出市场，或在明确确定的合理期限内召回该器械， 并将其传达给相关经济运营商。 Where, having performed an evaluation pursuant to Article 94, the competent authorities find that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall without delay require the manufacturer of the devices concerned, its authorised representative and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Regulation relating to the risk presented by the device and, in a manner that is proportionate to the nature of the risk, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

2. 主管机构应通过第 100 条所述的电子系统立即通知委员会、 其他成员国和根据第 56 条为有关器械颁发证书的公告机构，评估结果及其要求经济运营商采取的行动。 The competent authorities shall, without delay, notify the Commission, the other Member States and, where a certificate has been issued in accordance with Article 56 for the device concerned, the notified body that issued that certificate, of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 100.

3. 对于已投放至整个欧盟市场的所有相关器械，第 1 段中所述的经济运营商应立即确保在整个欧盟采取所有适当的纠正措施。 The economic operators as referred to in paragraph 1 shall, without delay, ensure that all appropriate corrective action is taken throughout the Union in respect of all the devices concerned that they have made available on the market.

4. 若第 1 段中所述的经济运营商在第 1 段所述期限内未采取适当的纠正措施，主管机构应采取一切适当措施，禁止或限制该器械出现在其国内市场，并将器械从该市场撤出或召回。 Where the economic operator as referred to in paragraph 1 does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the making available of the device on their national market, to withdraw the device from that market or to recall it.

主管机构应通过第 100 条所述电子系统，立即将这些措施通知委员会、其他成员国和本条第 2 段中所述的公告机构。The competent authorities shall notify the Commission, the other Member States and the notified body referred to in paragraph 2 of this Article, without delay, of those measures, by means of the electronic system referred to in Article 100.

5. 第 4 段所述的通知应包括所有可用的详细信息，特别是识别和追踪不合规器械所必需的数据、器械来源、器械不合规项的性质和原因以及相关风险、 所采取的国家措施的性质和持续时间、 以及相关经济运营商提出的争论。

The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.

6. 除启动程序的成员国以外的成员国应立即通过第 100 条所述的电子系统，向就任何其他有关器械不合规的相关信息以及其就有关器械采取的任何措施通知委员会和其他成员国。 Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 100, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned.

若与通告国家措施不一致， 应立即通过第 100 条所述电子系统通知委员会和其他成员国其反对意见。 In the event of disagreement with the notified national measure, they shall, without delay, inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 100.

7. 在收到第 4 段中所述的通知后的两个月内，倘若成员国或委员会均未对某一成员国所采取的任何措施提出反对意见，则此类措施应视为合理。 Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.

在这种情况下， 则所有成员国应确保立即对相关器械采取适当的限制性或禁止性措施， 包括撤回、 召回该器械，或限制其在全国市场上的流通。 In that case, all Member States shall ensure that corresponding appropriate restrictive or prohibitive measures, including withdrawing, recalling or limiting the availability of the device on their national market, are taken without delay in respect of the device concerned.

第 96 条

在欧盟层面评估国家措施的流程

Procedure for evaluating national measures at Union level

1. 在收到第 95(4) 条所述的通知后的两个月内， 倘若某一成员国对另一成员国采取的措施提出反对意见， 或委员会认为该措施违反欧盟法律，则在咨询相关主管机构和相关经济运营商（如有必要）后，委员会应评估该国家措施。基于该评估结果，委员会可通过实施细则来决议该国家措施是否合理。此外，应按照第 114(3) 条中述及的审查规程通过这些实施细则。 Where, within two months of receipt of the notification referred to in Article 95(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of

implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

2. 若委员会认为本条第 1 段所述的国家措施合理，则第 95(7) 条第二子段应适用。若委员会认为该国家措施不合理，则有关成员国应撤销该措施。 Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 95(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

在收到第 95(4) 条所述的通知后的八个月内，若委员会未按照本条第 1 段采纳一项决议，则该国家措施应视为合理。 Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 95(4), the national measure shall be considered to be justified.

3. 若某一成员国或委员会认为，某个器械对健康和安全造成的风险无法通过相关成员国采取的措施得到圆满解决，则委员会可在相关成员国的要求下或自行决议通过实施细则采取必要且正当合理的措施，以确保健康和安全得到保障，该措施包括限制或禁止将相关器械投放市场或投入使用。应按照第 114(3) 条中述及的审查规程通过这些实施细则。 Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 97 条

其他不合规项 Other non-compliance

1. 当根据第 94 条执行评估后，倘若某一成员国的主管机构发现某个器械不符合本法规规定的要求，但不对患者、使用者或其他人的健康和安全、或对保障公众健康的其他方面带来不可接受的风险，则该成员国可要求相关经济运营商在合理期限内解决相关不合规项，该期限应予以明确确定，并传达给经济运营商，同时与不符合性相称。 Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

2. 倘若经济运营商未在本条第 1 段所述的期限内解决该不符合性，则相关成员国应及时采取一切适当措施，限制或禁止该产品在市场上流通，或确保其从市场上召回或撤出。该成员国应通过第 100 条所述的电子系统立即通知委员会和其他成员国这些措施。 Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.

3. 为确保均适用本条规定，委员会可通过实施细则规定由主管机构采取的适当措施解决有关不合规项。应按照第 114(3) 条中述及的审查规程通过这些实施细则。 In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 98 条

预防性健康保护措施 Preventive health protection measures

1. 若成员国在进行了表明与器械或特定类别或器械组相关的潜在风险评估之后认为，为保护患者、使用者或其他人员的健康和安全或公共卫生其他方面，应禁止、限制或遵守特定要求，方可在市场上出售或使用器械或特定类别或器械组，或应采取任何必要和正当措施从市场撤出或召回这种器械或类别或器械组。 Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices, considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.

2. 第 1 段中所述的成员国应通过第 100 条所述的电子系统，立即通知委员会和所有其他成员国，说明做出决议的理由。 The Member State referred to in paragraph 1 shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 100.

3. 委员会应与 MDCG 或有关经济运营商 （必要时）咨询，对采取的国家措施进行评估。委员会可通过实施细则来决议该国家措施是否合理。倘若委员会未于其通知后的六个月内进行决议，则该国家措施应视为合理。应按照第 114(3)条中述及的审查规程通过这些实施细则。 The Commission, in consultation with the MDCG and, where necessary, the economic operators concerned, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision within six months of their notification, the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

4. 倘若本条第 3 段所述的评估表明，为保障患者、使用者或其他个人的健康和安全或公众健康的其他方面，应禁止或限制某个器械或特定的器械类别或分组在市场上流通或投入使用，或应使其服从特定要求，或应将此类器械或器械类别或分组从市场上撤出或从各成员国中召回，则委员会应采取适当合理的措施。可根据第 114(3)条所述的审查程序采取执行实施细则。 Where the assessment referred to in paragraph 3 of this Article demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts to take the necessary and duly justified measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 99 条

良好行政管理规定实践 **Good administrative practice**

1. 对于成员国主管机构根据第 95 条至 98 条的规定采取的任何措施，应说明其所依据的确切理由。若该措施针对某个特定的经济运营商，则主管机构应立即通知相关经济运营商有关该措施，同时向其告知经济运营商法律或相关成员国的行政管理规定实践项下的可用补救措施、以及此类补救措施的期限。若该项措施普遍适用，则应进行适当公布。 Any measure adopted by the competent authorities of the Member States pursuant to Articles 95 to 98 shall state the exact grounds on which it is based. Where such a measure is addressed to a specific economic operator, the competent authority shall notify without delay the economic operator concerned of that measure, and shall at the same time inform that economic operator of the remedies available under the law or the administrative practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general applicability, it shall be appropriately published.

2. 除了因对人类健康或安全带来不可接受的风险而必需采取即时行动情况之外，在采用任何措施之前，应给予相关经济运营商机会，以便于明确确定的适当期限内向主管机构提交意见书。 Except in cases where immediate action is necessary for reasons of unacceptable risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time that is clearly defined before any measure is adopted.

若在经济运营商未获得第一子段中所述的提交机会的情况下采取行动，则应给予该经济运营商机会，以尽快提出意见，随后应立即对已采取的行动进行审查。 Where action has been taken without the economic operator having had the opportunity to make submissions as referred to in the first subparagraph, it shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.

3. 一旦经济运营商证明其已采用更为有效的纠正措施，且该器械已符合本法规的要求，则应立即撤回或修订已采取的措施。 Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that it has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.

若根据第 95 条至第 98 条采取的措施涉及某一公告机构参与符合性评估的器械，主管机构应通过第 100 条所述的电子系统通知相关的公告机构和公告机构上级主管机构其已采取的措施。 Where a measure adopted pursuant to Articles 95 to 98 concerns a device for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 100 inform the relevant notified body and the authority responsible for the notified body of the measure taken.

1. Article 100

第 100 条

市场监管中的电子系统

Electronic system on market surveillance

1. 委员会应与成员国合作，建立并管理一套电子系统，以收集和处理以下信息： The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:

（a） 第 93（4）条所指监管活动结果的总结； summaries of the results of the surveillance activities referred to in Article 93(4);

（b） 第 93 条（7）中所述的最终报告 the final inspection report referred to in Article 93(7);

（c） 第 95（2）、（4）和第（6）条中所述的可能对健康和安全带来不可接受风险的器械的相关信息； information in relation to devices presenting an unacceptable risk to health and safety as referred to in Article 95(2), (4) and (6);

（d） 关于第 97(2)条所述产品不合规的信息； information in relation to non-compliance of products as referred to in Article 97(2);

（e） 第 98（2）条中所述的预防性卫生保护措施的相关信息； information in relation to the preventive health protection measures referred to in Article 98(2);

（f） 第 93(8)条所述成员国监管活动的审查和评估结果总结。 summaries of the results of the reviews and assessments of the market surveillance activities of the Member States referred to in 93(8).

2. 本条第 1 段中所述的信息应立即通过电子系统传送给所有相关主管机构，并在适用时，传送至根据第 56 条为有关器械颁发证书的公告机构并向成员国和委员会开放。 The information referred to in paragraph 1 of this Article shall be immediately transmitted through the electronic system to all competent authorities concerned and, where applicable, to the notified body that issued a certificate in accordance with Article 56 for the device concerned and be accessible to the Member States and to the Commission.

3. 当可能影响成员国之间的市场监管活动与合作时，成员国之间交换的信息不得对外公开。 Information exchanged between Member States shall not be made public where to do so might impair market surveillance activities and co-operation between Member States.

第 VIII 章 CHAPTER VIII

成员国、医疗器械协调小组、专家实验室、专家小组和器械注册机构之间的合作 COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

第 101 条

主管机构 Competent authorities

成员国应指定主管机构或负责本法规的实施的官方机构。 成员国应根据本法规的要求向其机构授予所需的权力、 资源、设备和知识，以便适当履行其任务。成员国应向委员会告知主管机构的名称和联系方式，再由委员会公布主管机构名单。 The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.

第 102 条

协作 Cooperation

1. 成员国的主管机构应相互合作， 并与委员会合作。 委员会应提供组织交流的必要信息， 使本法规统一适用。 The competent authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to enable this Regulation to be applied uniformly.

2. 成员国应在委员会的支持下，在适当时候参与国际层面的倡议，以确保监管机构在医疗器械领域开展合作。 Member States shall, with the support of the Commission, participate, where appropriate, in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

第 103 条 Article 103

医疗器械协调小组 Medical Device Coordination Group

1. 特此建立医疗器械协调小组 （MDCG ）。A Medical Device Coordination Group (‘ MDCG’) is hereby established.

2. 各成员国应任命 MDCG 的一名具有医疗器械领域专业知识成员和候补成员， 以及一名具有体外诊断医疗器械领域专业知识的成员和候补成员任期三年且可延长任期。成员国可选择只任命一名具有这两个领域专门知识的成员和候补成员。 Each Member State shall appoint to the MDCG, for a three-year term which may be renewed, one member and one alternate each with expertise in the field of medical devices, and one member and one alternate with expertise in the field of in vitro diagnostic medical devices. A Member State may choose to

appoint only one member and one alternate, each with expertise in both fields.

应根据其在医疗器械和体外诊断医疗器械领域的能力和经验选择 MDCG 的成员。其应代表成员国的主管机构。成员的名称和所属机构应由委员会公布。 The members of the MDCG shall be chosen for their competence and experience in the field of medical devices and in vitro diagnostic medical devices. They shall represent the competent authorities of the Member States. The names and affiliation of members shall be made public by the Commission.

在成员缺席时，候补成员应代表其并投票。 The alternates shall represent and vote for the members in their absence.

3. MDCG 应根据委员会或成员国的要求定期举行会议，并视情况需要举行会议。这些会议应由在医疗器械领域任职的成员或专家，或在体外诊断医疗器械领域任职的专家，或任命具有这两个领域专门知识的成员或其候补成员出席。 The MDCG shall meet at regular intervals and, where the situation requires, upon request by the Commission or a Member State. The meetings shall be attended either by the members appointed for their role and expertise in the field of medical devices, or by the members appointed for their expertise in the field of in vitro diagnostic medical devices, or by the members appointed for their expertise in both fields, or their alternates, as appropriate.

4. MDCG 应尽最大努力达成共识。 若不能达成这样的共识， MDCG 将由其多数成员决议。 具有不同职位的成员可申请其职位， 而其所依据的理由将记录在 MDCG 的职位上。 The MDCG shall use its best endeavours to reach consensus. If such consensus cannot be reached, the MDCG shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the MDCG's position.

5. MDCG 应由委员会的一名代表担任主席。主席不得参加 MDCG 的投票。 The MDCG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the MDCG.

6. MDCG 可根据具体情况邀请专家和其他第三方参加会议或提供书面文稿。 The MDCG may invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.

7. MDCG 可建立常设或临时分小组。在适当情况下，应在欧盟级别以观察员身份邀请代表医疗器械行业、医疗保健专业人员、实验室、患者和消费者利益的组织参加这些分小组。 The MDCG may establish standing or temporary sub-groups. Where appropriate, organisations representing the interests of the medical device industry, healthcare professionals, laboratories, patients and consumers at Union level shall be invited to such sub-groups in the capacity of observers.

8. 应制定其议事规则，尤其应规定以下流程： The MDCG shall establish its rules of procedure which shall, in particular, lay down procedures for the following:

- 包括在紧急情况下采纳意见或建议或其他立场； the adoption of opinions or recommendations or other positions, including in cases of urgency;
- 将任务委托给报告和共同报告成员； the delegation of tasks to reporting and co-reporting members;
- 执行关于益利冲突的第 107 条； the implementation of Article 107 regarding conflict of interests;
- 分小组的功能。 the functioning of sub-groups.

9. MDCG 应执行本 2017/746 号法规第 105 条和第 99 条规定的任务。

The MDCG shall have the tasks laid down in Article 105 of this Regulation and Article 99 of Regulation (EU) 2017/746.

第 104 条

委员会的支持 **Support by the Commission**

委员会应为国家主管机构之间合作提供支持。其应特别规定主管机构之间交流经验，并向 MDCG 及其分小组提供技术、科学和后勤支持。它应组织 MDCG 及其分小组的会议，参加这些会议并确保适当的跟踪。 The Commission shall support the functioning of the cooperation between national competent authorities. It shall, in particular, provide for the organisation of exchanges of experience between the competent authorities and provide technical, scientific and logistic support to the MDCG and its sub-groups. It shall organise the meetings of the MDCG and its sub-groups, participate in those meetings and ensure the appropriate follow-up.

第 105 条

MDCG 的任务 Tasks of the MDCG

根据本法规， MDCG 的工作任务如下： Under this Regulation, the MDCG shall have the following tasks:

(a) 根据第 IV 章规定，帮助评估申请人符合性评估机构和公告机构； to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;

(b) 应委员会要求， 就根据第 49 条设立的公告机构协调小组的事项向委员会提供咨询意见； to advise the Commission, at its request, in matters concerning the coordination group of notified bodies as established pursuant to Article 49;

(c) 协助制定旨在确保协调有效地执行本法规的指导，尤其是关于指定和监测公告机构，应用通用安全与性能要求以及进行临床评价和制造商的研究，公告机构和警戒活动进行的评估； to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of clinical evaluations and investigations by manufacturers, assessment by notified bodies and vigilance activities;

(d) 为持续监测技术进展并评估本法规和 2017/746 号法规规定的通用安全与性能要求是否可确保器械的安全和性能，并有助于确定是否需要修订本法规附录 I；to contribute to the continuous monitoring of technical progress and assessment of whether the general safety and performance requirements laid down in this Regulation and Regulation (EU) 2017/746 are adequate to ensure safety and performance of devices, and thereby contribute to identifying whether there is a need to amend Annex I to this Regulation;

(e) 促进器械标准、 CS 和科学指南的发展， 包括产品特定指南， 尤其是可植入和 III 类器械的某些器械的临床研究； to contribute to the development of device standards, of CS and of scientific guidelines, including product specific guidelines, on clinical investigation of certain devices in particular implantable devices and class III devices;

(f) 根据第 93 条协助成员国主管机构开展其协调活动， 尤其是在器械分类和确定法规现状、 临床研究、 警戒和市场监管等领域，包括制定和维持欧洲市场监管方案框架，旨在确保欧盟市场监管的效率和协调； to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and the determination of the regulatory status of devices, clinical investigations, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance programme with the objective of achieving efficiency and harmonisation of market surveillance in the Union, in accordance with Article 93

(g) 在本法规实施的任何相关问题评估中， 主动或在委员会的要求下， 提供意见； to provide advice, either on its own initiative or at request of the Commission, in the assessment of any issue related to the implementation of this Regulation;

(h) 在成员国境内， 促进器械的协调行政管理规定。 to contribute to harmonised administrative practice with regard to devices in the Member States.

第 106 条

提供科学、技术和临床意见和建议

Provision of scientific, technical and clinical opinions and advice

1. 委员会应通过实施细则并与 MDCG 磋商，委任专家小组，评估本条第 9 段所述的相关医疗领域的临床研究，并根据 2017/746 号法规 /第 48（6）条，就某些体外诊断医疗器械性能评估，以及（如必要）针对器械类别或器械组，或者与之相关的特定危害，按照最高科学能力、公正性、独立性和透明度等原则，发表自己的意见。当委员会决议按照本条第 7 段任命专家实验室时，适用同样原则。 The Commission shall, by means of implementing acts and in consultation with the MDCG, make provision for expert panels to be designated for the assessment of the clinical evaluation in relevant medical fields as referred to in paragraph 9 of this Article and to provide views in accordance with Article 48(6) of Regulation (EU) 2017/746 on the performance evaluation of certain in vitro diagnostic medical devices and, where necessary, for categories or groups of devices, or for specific hazards relating to categories or groups of devices, observing the principles of highest scientific competence, impartiality, independence and transparency. The same principles shall apply where the Commission decides to appoint expert laboratories in accordance with paragraph 7 of this Article.

2. 可在委员会与 MDCG 协商确定需要提供一致的科学、技术和 /或临床建议或实施本法规实验室专业知识等领域任命专家小组和专家实验室。可任命常设或暂时的专家小组和专家实验室。 Expert panels and expert laboratories may be designated in areas where the Commission, in consultation with the MDCG, has identified a need for the provision of consistent scientific, technical and/or clinical advice or laboratory expertise in relation to the implementation of this Regulation. Expert panels and expert laboratories may be appointed on a standing or temporary basis.

3. 专家小组应由委员会根据领域内最新的临床、科学或技术专门知识任命的顾问，以及反映欧盟科学和临床方法多样性的地理分布组成。委员会应根据必要性，确定各小组的成员人数。 Expert panels shall consist of advisors appointed by the Commission on the basis of up-to-date clinical, scientific or technical expertise in the field and with a geographical distribution that reflects the diversity of scientific and clinical approaches in the Union. The Commission shall determine the number of members of each panel in accordance with the requisite needs.

   专家小组成员应以公正和客观的态度履行其任务。其不得寻求或接受公告机构或制造商的指示。各成员应制定一项公开的利益声明。 The members of expert panels shall perform their tasks with impartiality and objectivity. They shall neither seek nor take instructions from notified bodies or manufacturers. Each member shall draw up a declaration of interests, which shall be made publicly available.

   委员会应建立体系和流程，积极管理和预防潜在的利益冲突。 The Commission shall establish systems and procedures to actively manage and prevent potential conflicts of interest.

4. 专家小组在提出其科学观点时应考虑利益相关者提供的相关信息，包括患者组织和医疗保健专业人员。 Expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions

5. 委员会在与 MDCG 咨询后，在《欧盟官方报》上和委员会网站上公布信息并征求意向书后，可任命专家小组顾问。根据任务类型和具体专业知识的需要，可任命专家小组顾问，任期最长为三年且其任命可续期。 The Commission, following consultation with the MDCG, may appoint advisors to expert panels following publication in the Official Journal of the European Union and on the Commission website following a call for expressions of interest. Depending on the type of task and the need for specific expertise, advisors may be appointed to the expert panels for a maximum period of three years and their appointment may be renewed.

6. 委员会在与 MDCG 咨询之后，可将顾问加入一份中心专家名单，其在没有正式任命为专家小组的情况下可提供咨询意见，并根据需要来支持专家小组的工作。该名单应在委员会网站上公布。 The Commission, following consultation with the MDCG, may include advisors on a central list of available experts who, whilst not being formally

appointed to a panel, are available to provide advice and to support the work of the expert panel as needed. That list shall be published on the Commission website.

7. 委员应在实施细则并在会在与 MDCG 咨询之后，根据其在特定器械、类别或器械组的 The Commission may, by means of implementing acts and following consultation with the MDCG, designate expert laboratories, on the basis of their expertise in:

- 物理化学特性或 physico-chemical characterisation, or
- 微生物学、 生物相容性、 机械、 电学、电子或非临床生物和毒理学测试 microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing of specific devices, categories or groups of devices.

委员会只应指定一个成员国或联合研究中心提交了指定申请的专家实验室。 The Commission shall only designate expert laboratories for which a Member State or the Joint Research Centre has submitted an application for designation.

8. 专家实验室应满足以下标准： Expert laboratories shall satisfy the following criteria:

(a) 拥有足够和合资格的工作人员，在其受托的器械领域具有足够的知识和经验； have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the devices for which they are designated;

(b) 拥有必要的设备来执行分配给其任务； possess the necessary equipment to carry out the tasks assigned to them;

(c) 具有国际标准和最佳方案的必要知识； have the necessary knowledge of international standards and best practices;

(d) 具有适当的行政组织和结构； have an appropriate administrative organisation and structure;

(e) 确保其工作人员在执行任务时遵守所获信息和数据的保密性规定； ensure that their staff observe the confidentiality of information and data obtained in carrying out their tasks

9. 任命在相关医疗领域进行临床研究的专家小组应完成第 54（1）和 61（2）条以及附录 IX 第 5.1 节或附录 X 第 6 节指定的任务（如适用） 。Expert panels appointed for clinical evaluation in relevant medical fields shall fulfil the tasks provided for in Article 54(1) and Article 61(2) and Section 5.1 of Annex IX or Section 6 of Annex X, as applicable.

10. 专家小组和专家实验室可能具有以下任务, 具体取决于必要的需求： Expert panels and expert laboratories may have the following tasks, depending on the requisite needs:

(a) 为委员会和 MDCG 在有关本法规实施方面提供科学、 技术和临床援助； to provide scientific, technical and clinical assistance to the Commission and the MDCG in relation to the implementation of this Regulation;

(b) 有助于制定和维护适当的指导和 CS 用于特定器械或一类或一组器械 to contribute to the development and maintenance of appropriate guidance and CS for:

- 临床研究， clinical investigations,
- 临床评价和 PMCF， clinical evaluation and PMCF,
- 性能研究， performance studies,
- 性能评估和上市后性能跟踪, erformance evaluation and post-market performance follow-up,
- 物理化学特征，以及 physico-chemical characterisation, and
- 微生物、生物相容性、机械、电气、电子或非临床毒理学试验 microbiological, biocompatibility,

mechanical, electrical, electronic or non-clinical toxicological testing

for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices;

(c) 制定和审查适用于符合性评估流程的现有性能，涉及到临床评价、性能评估、物理化学特征、微生物、生物相容性、 机械、电气、电子和非临床毒理学试的临床研究指导和性能研究指导原则验； to develop and review clinical evaluation guidance and performance evaluation guidance for performance of conformity assessment in line with the state of the art with regard to clinical evaluation, performance evaluation, physico-chemical characterisation, and microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical toxicological testing;

(d) 有助于制定国际水平标准, 确保该等标准反映最先进技术； to contribute to the development of standards at international level, ensuring that such standards reflect the state of the art;

(e) 根据制造商按照第 61（2），公告机构和成员国根据本条第 11 至 13 段进行的磋商提出意见。 to provide opinions in response to consultations by manufacturers in accordance with Article 61(2), notified bodies and Member States in accordance with paragraphs 11 to 13 of this Article.

(f) 有助于确定医疗器械安全与性能相关及新出现的问题； to contribute to identification of concerns and emerging issues on the safety and performance of medical devices;

(g) 根据关于特定体外诊断医疗器械性能评估的 2017/746 号法规第 48（4）条提供观点。 to provide views in accordance with Article 48(4) of Regulation (EU) 2017/746 on the performance evaluation of certain in vitro diagnostic medical devices.

11. 委员会应促进成员国以及公告机构和制造商获得相关专家小组和专家实验室提供的建议，尤其是关于器械符合性评估适当数据集的标准，特别是关于临床评价所需的临床数据以及关于物理化学特征以及微生物学、生物相容性、机械、电气、电子和非临床毒理学试验。 The Commission, shall facilitate the access of Member States and notified bodies and manufacturers to advice provided by expert panels and expert laboratories concerning, inter alia, the criteria for an appropriate data set for assessment of the conformity of a device, in particular with regard to the clinical data required for clinical evaluation, with regard to physico-chemical characterisation, and with regard to microbiological, biocompatibility, mechanical, electrical, electronic and non-clinical toxicological testing.

12. 当根据第 9 段采用其科学意见时，专家小组的成员应尽其最大努力来达成共识。若无法达成共识，则专家小组应由其大多数成员决议, 并且科学意见应所述分歧立场及其基于的理由。 When adopting its scientific opinion in accordance with paragraph 9, the members of the expert panels shall use their best endeavours to reach consensus. If consensus cannot be reached, the expert panels shall decide by a majority of their members, and the scientific opinion shall mention the divergent positions and the grounds on which they are based.

委员会应公布根据本条第 9 和 11 段传递的科学意见和建议, 确保考虑到第 109 条的保密性问题。 应在与 MDCG 咨询之后公布第 10 段（c）点所述的临床评价指南。 The Commission shall publish the scientific opinion and advice delivered in accordance with paragraphs 9 and 11 of this Article, ensuring consideration of aspects of confidentiality as set out in Article 109. The clinical evaluation guidance referred to in point (c) of paragraph 10 shall be published following consultation with the MDCG.

13. 委员会应要求制造商和公告机构向专家小组和专家实验室提供的建议向支付费用。在考虑到充分实施本法规、健康和安全性保护、支持创新和成本收益以及必须实现专家小组积极参与的目标下，应由委员会通过实施细则来采用费用尺度和结构以及可收回成本的规模和结构。并且应根据第 114（3）条所述的审查程序通过实施细则。 The Commission may require manufacturers and notified bodies to pay fees for the advice provided by expert panels and expert laboratories. The structure and the level of fees as well as the scale and structure of recoverable costs

shall be adopted by the Commission by means of implementing acts, taking into account the objectives of the adequate implementation of this Regulation, protection of health and safety, support of innovation and cost-effectiveness and the necessity to achieve active participation in the expert panels. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

14. 按照本条第 13 段的规程规定应付给委员会的费用应以透明的方式设定，并且基于所提供服务的成本，并在根据附录 IX 第 5.1 节（c）点（关于第 2003/361/EC 号建议所定义的微型、小型或中型企业的制造商）发起的临床评价咨询规程的情况下，应减少应付费用。The fees payable to the Commission in accordance with the procedure under paragraph 13 of this Article shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with point (c) of Section 5.1 of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

15. 根据第 115 条，委员会应有权采用授权的法案，修订本条第 10 段中所述的专家小组和专家实验室的任务。The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the tasks of expert panels and expert laboratories referred to in paragraph 10 of this Article.

第 107 条

利益冲突 Conflict of interests

1. MDCG 的成员、其分小组以及专家小组和专家实验室的成员不得在医疗器械行业具有可能影响其公正性的财务或其他利益。其应承诺出于公共利益并且以独立的方式行事。其应宣布其可能在医疗器械行业具有的任何直接或间接利益，并且每当相关变化发生时，更新此声明。应在委员会网站上公开利益声明。本条规定不适用于参与 MDCG 分小组的利益相关者组织的代表。Members of the MDCG, its sub-groups, and members of expert panels and expert laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct or indirect interests they may have in the medical device industry and update that declaration whenever a relevant change occurs. The declaration of interests shall be made publicly available on the Commission website. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. 由 MDCG 以逐案的基准邀请的专家和其他第三方应宣布其可能在问题事项中的任何利益。Experts and other third parties invited by the MDCG on a case-by-case basis shall declare any interests they may have in the issue in question.

第 108 条

器械注册机构和数据库 Device registers and databanks

委员会和成员国应采取一切适当措施来鼓励建立特定类型器械的登记表和数据库，设定通用原则来收集可比较的信息。此类登记表和数据库应有助于器械长期安全性以及性能，或者可植入器械可追溯性或所有此类特征的独立评估。

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and databanks for specific types of devices setting common principles to collect comparable information. Such registers and databanks shall contribute to the independent evaluation of the long-term safety and performance of devices, or the traceability of implantable devices, or all of such characteristics

第 IX 章

机密性、数据保护、资金来源及处罚

CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

第 109 条

机密性 Confidentiality

1. 除非本法规另有规定，且不影响成员国现有国家保密条款和惯例，否则，所有适用本法规的成员应在执行任务时遵守信息和所获数据的保密性规定，以保护以下内容： Unless otherwise provided for in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

   (a) 符合第 110 条规定的个人数据； personal data, in accordance with Article 110;

   (b) 自然人或法人的商业保密信息和商业秘密，包括知识产权；符合公共利益的披露除外； commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights; unless disclosure is in the public interest;

   (c) 本法规的有效执行，特别是以检查、调查或审计为目的。 the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. 在不影响第 1 段规定的情况下，未经发起机构事先同意，不得披露主管机构之间、主管机构与委员会之间处于保密状态的交流信息。 Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. 第 1 和 2 段不得影响委员会、成员国和公告机构在信息交流和警戒信息传播方面的权利和义务，也不得影响根据刑法提供信息的有关人员的义务。 Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. 委员会和成员国可与签订双边或多边保密协议的第三方监管机构交流机密信息。 The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

第 110 条

数据保护 Data protection

1. 成员国应适用第 95/46/EC 号指令，根据本法规规定在成员国内处理个人数据。 Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. 第 EC 45/2001 号法规应适用于委员会按照本法规进行的个人数据处理。 Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

第 111 条

收费 Levying of fees

1. 若费用水平透明，且基于成本回收原则，本规例不妨碍成员国就本法规所规定活动所征收的费用。 This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of

cost-recovery principles.

2. 成员国应在采纳费用构成和收费水平前至少三个月通知委员会和其他成员国。费用结构和水平应按要求公开。Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

第 112 条

指定公告机构和监控活动的资金

Funding of activities related to designation and monitoring of notified bodies

委员会应通过实施细则规定可回收成本的比例和结构以及其他必要的实施细则。 应按照第 114(3)条中述及的审查流程来通过这些实施细则。 The costs associated with joint assessment activities shall be covered by the Commission. The Commission shall, by means of implementing acts, lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).

第 113 条

处罚 **Penalties**

各成员国应制定适用于违反本法规规定情况的处罚规定，并应采取一切必要措施，确保这些规定的实施。规定的惩罚应当有效、适度和具有劝阻性。成员国应在 2020 年 2 月 25 日前就此类条款规定通知委员会有关规定和措施，且应及时通知，以免影响任何后续修订。 The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by 25 February 2020 and shall notify it, without delay, of any subsequent amendment affecting them.

第 **X** 章

最终条款 **FINAL PROVISIONS**

第 114 条

委员程序 **Committee procedure**

1. 委员会应由医疗器械委员会进行协助。 该委员会为欧盟第 182/2011 号法规中所指委员会。 The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. 若该段应引用参考资料， 则应适用欧盟第 182/2011 号法规第 4 条。Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. 若该段应引用参考资料， 则应适用欧盟第 182/2011 号法规第 5 条。Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

   若委员不发表意见， 则委员会不得通过实施细则草案， 且应适用欧盟第 182/2011 号法规第 5(4)条中的第三子段。Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. 参考本段时， 同样适用欧盟第 182/2011 号法规第 8 条及第 4 或 5 条（如适用）。Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate,

shall apply.

第 115 条

授权 **Exercise of the delegation**

1. 根据本条款规定，授予委员会实施授权的权力。 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. 第 1(5)、3、10(4)、18(3)、19(4)、27(10)、44(11)、52(5)、56(6)、61(8)、70(8)和 106(15)条所述采取授权行为的权力应自 2017 年 5 月 25 日起授予委员会，其有效期为 5 年。委员会应在 5 年有效期结束前至少 9 个月就所授权力起草一份报告。默认转授权力应延长相同的期限，除非欧洲议会或者理事会在各期限结束前三个月反对此类延时。 The power to adopt delegated acts referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. 第 1(5)、3、10(4)、18(3)、19(4)、27(10)、44(11)、52(5)、56(6)、61(8)、70(8)和 106(15)条所述授权可由欧洲议会或者理事会随时撤销。撤销决议将终止该决议中指定的权力授予。其生效日期应当为欧盟官方公告发表该决议后或者在决议规定的一个后续日期。它对已生效的授权法案效力无任何影响。 The delegation of power referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. 采取授权行为之前，委员会应根据改善立法机构于 2016 年 4 月 13 日签署的《机构间协议》所规定的原则，咨询各成员国指定的专家。 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. 在采用授权法案之后，委员会应同时通知欧洲议会和理事会。 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. 按照第 1(5)、3、10(4)、18(3)、19(4)、27(10)、44(11)、52(5)、56(6)、61(8)、70(8)和 106(15)条通过的授权法案只有在欧洲议会或理事会在收到该法案通知后三个月内未表示反对，或者在此期限期满前欧洲议会和理事会都通知委员会表示自己不反对时方可生效。欧洲议会或理事会可主动将此期限延长三个月。 A delegated act adopted pursuant to Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

第 116 条

不同授权的单独授权行为 **eparate delegated acts for different delegated powers**

委员会应就根据本法规授予其每项权力采取单独的授权行为。 The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation

第 117 条

第 **2001/83/EC** 号指令修订案 **Amendment to Directive 2001/83/EC**

在第 2001/83/EC 号指令的附录 I 中，第 3.2 节第 12 点替换为以下内容： In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

“（12）若根据欧洲议会和理事会 2017/746 号法规第 1（8）条第二子段或第 1(9)条第二子段，产品受此指令管辖，则上市许可档案应包括（如可用）器械零部件符合性评估的结果以及制造商的 EC 符合性声明或公告机构发行的相关证书包含的此法规附录 I 的安全性和性能一般要求，以便允许制造商将 CE 标识贴附到医疗器械上。 Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council (*1), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

若档案不包括在第一子段中所述的符合性评估结果，并且若对于器械（若分别使用）的符合性评估，根据 2017/745 号法规需要公告机构参与，则管理机构应要求申请人根据问题器械类型适用法规指定的公告机构发布的此法规附录 I 相关的安全性和性能一般要求的符合性，就器械零部件与提出意见。 f the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question

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***** 欧洲议会和欧洲委员会于 2017 年 4 月 5 日签发的关于医疗器械的第 2017/746 号法规，修订了第 2001/83/EC 指令、第 178/2002 号法规和第 1223/2009 号法规，并废除了理事会第 90/385/EEC 号指令和第 93/42/EEC 号指令（ OJ L117, 5.5.2017, p. 1) 。”

第 118 条

欧洲委员会第 **178/2002** 号法规修订案 Amendment to Regulation (EC) No 178/2002

在第 178/2002 号法规第 2 条第三子段中，添加以下各段： In the third paragraph of Article 2 of Regulation (EC) No 178/2002, the following point is added:

“ (i) 欧洲议会和理事会第 2017/745 号法规规定的医疗器械 （*）。medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council (*2).

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(*) 2017 年 4 月 5 日欧洲议会和欧洲委员会关于医疗器械的第 2017/745 号法规，修订了第 2001/83/EC 指令、第 178/2002 号法规和第 1223/2009 号法规，并废除了理事会第 90/385/EEC 号和第 93/42/EEC 号指令 (OJ L 117, 5.5.2017, p. 1)。”

第 119 条

欧洲委员会第 **1223/2009** 号法规修订案 **Amendment to Regulation (EC) No 1223/2009**

在第 1223/2009 号（ EC）法规第 2 条中，添加以下各段： In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

“ 4. 委员会可按照成员国的请求或自主行动，采用必要的措施确定特定产品或产品组是否处于“ 美容产品 ” 定义范围内。并应根据第 32(2) 条所述的监管规程采用这些措施。 ” The Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition ‘ cosmetic product ’. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 32(2). ’

第 120 条

过渡性条款 Transitional provisions

1. 自 2020 年 5 月 26 日起，公告机构根据第 90/385/EEC 和 93/42/EEC 号指令发布的任何通知将失效。 From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2. 在 2017 年 5 月 25 日前根据第 90/385/EEC 和 93/42/EEC 号指令由公告机构发行的证书应保持有效，直至证书所示的期限结束，除了根据第 90/385/EEC 号指令附录 4 或第 93/42/EEC 号指令附录 IV 颁发的证书（其应于 2022 年 5 约 7 日自动失效）。Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.

   自 2017 年 5 月 25 日起根据第 90/385/EEC 和 93/42/EEC 号指令由公告机构发行的证书应保持有效，直至证书所示的期限结束，从其交付日期起有效期不得超过五年。但其应于 2024 年 5 月 27 日失效。 Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

3. 为豁免本规则第 5 条规定，具有根据第 90/385/EEC 号指令或第 93/42/EEC 号指令颁发的以及本条第 2 段规定有效证书的器械仅能投放市场或投入使用，前提是从本法规适用之日起，此类器械仍遵守这些指令中的任一条，且设计和预期目的无重大变化。但本法规关于上市后监督、市场监督、警惕、经济运营商和器械注册的要求应适用于这些指令中的相应要求。 By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

   在不影响本条第 IV 章和第 1 段的情况下，颁发第一子段所述证书的公告机构应继续负责对与其认证器械相关的所有适用要求进行适当监督。 Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

4. 根据第 90/385/EEC 号指令和第 93/42/EEC 号指令在 2022 年 5 月 26 日前合法投放市场的器械，以及自 2020 年 5 月 26 日起投放市场并具有本条第 2 段所述证书的器械，可继续在市场上提供或投入使用，直至 2025 年 5 月 26 日。 Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.

5. 通过豁免第 90/385/EEC 和 93/42/EEC 号指令的方式，符合本法规的器械可在 2020 年 5 月 26 日前投放市场。 By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

6. 通过豁免第 90/385/EEC 和 93/42/EEC 号指令的方式，可在 2020 年 5 月 26 日前指定并通知符合该法规的符合性评估机构。根据本法规指定并通知的公告机构，可在 2020 年 5 月 26 日前，采用其规定的符合性评估流程并按照本法规规定签发证书。 By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity

assessment bodies which comply with this Regulation may be designated and notified prior 26 May 2020. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.

7. 对于受限于第 54 条规定咨询规程的器械, 本条第 5 段应适用, 前提是已委派必要的 MDCG 、专家小组。 As regards devices subject to the consultation procedure laid down in Article 54, paragraph 5 of this Article shall apply provided that the necessary appointments to the MDCG and expert panels have been made.

8. 分别根据第 90/385/EEC 号指令的第 10a 条或第 93/42/EEC 号指令的第 14(1)和（2）条以及分别根据第 90/385/EEC 号指令第 10b（1）条第（ a）点或第 93/42/EEC 号指令第 14a（1）条第（ a）和（ b）点, 按照第 2010/227/EU 号决议的规定, 通过豁免第 90/385/EEC 号指令的第 10a 条和第 10b（1）条第（ a）点以及第 93/42/EEC 号指令的第 14(1)和（2）条和第 14a（1）条的第（ a）和（b）点, 在第 123（3）条（d）点所述日期和 18 个月结束期限内（以较晚者为准）, 符合本法规的第 29（4）和 56（5）条的制造商、授权代表、进口商和公告机构应视为符合成员国的法律法规。 By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to point (d) of Article 123(3) and ending 18 months later, comply with Article 29(4) and Article 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Decision 2010/227/EU.

9. 成员国主管机构根据第 90/385/EEC 号指令第 9(9) 条或 93/42/EEC 号指令第 11(13)条的授权在授权所注明期限内应继续有效 Authorisations granted by the competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

10. 根据第 1(6) 条（ f）点和（ g）点, 在本法规范围内且在 2020 年 5 月 26 日前根据成员国的有效规则合法投放市场或投入使用的器械可继续投放市场以及可在有关成员国投入使用。 Devices falling within the scope of this Regulation in accordance with points (f) and (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020 may continue to be placed on the market and put into service in the Member States concerned.

11. 根据第 90/385/EEC 号指令第 10 条或第 93/42/EEC 号指令第 15 条在 2020 年 5 月 26 日前已开始执行的临床研究可继续进行。 但自 2020 年 5 月 26 日起, 应根据本法规进行严重不良事件和器械缺陷的报告。 Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

12. 在委员会根据第 27(2)条指定发行实体前, GS1、 HIBCC 和 ICCBBA 应被视为指定的发行实体。 Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

第 121 条

评估 Evaluation

在 2027 年 5 月 27 日之前，委员会应评估本法规的应用，并就实现法规目标的进展制定评估报告，包括实施本法规所需的资源评估。依据第 27 条，经济运营商、健康机构和健康专家应特别注意通过 UDI 对存储的器械进行追溯。 By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this

Regulation. Special attention shall be given to the traceability of medical devices through the storage, pursuant to Article 27, of the UDI by economic operators, health institutions and health professionals.

第 122 条

废除 **Repeal**

在不影响本法规第 120（3）和（ 4）条规定以及在不影响成员国和制造商的警惕义务方面以及制造商在提供文件方面义务的情况下， 自 2020 年 5 月 26 日起，废除理事会第 90/385/EEC 和 93/42/EEC 号指令，例外情况为 Without prejudice to Articles 120(3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2020, with the exception of:

- 在本法规第 123(3)条（ d）点所述的两个日期之后（以较晚的为准） ，废除第 90/385/EEC 号指令的第 8 条、第 10 条、第 10b（1）条的第（ b）和（ c）点、第 10b（2）条和第 10b（3）条，以及相应附录中规定与警惕和临床研究有关的义务。 Articles 8 and 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation;
- 自本法规第 123(3)条（ d）点条所述两个日期中较晚日期后 18 个月起，废除第 90/385/EEC 号指令第 10a 条和第 10b(1)条（ a）点，以及与器械和经济运营商注册有关的义务及相应附录中规定的证书通知。 Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation;
- 自本法规第 123(3)条（ d）点所述的两个日期之后 （以较晚的为准） ，废除第 93/42/EEC 号指令第 10 条、第 14a(1)条第 (c)和(d)点、第 14a(2)条、第 14a(3)条以及第 15 条自第 97(2)条和第 97(3)(ba)条，以及相应附录中规定与警惕和临床研究有关的义务。 Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation; and
- 自本法规第 123(3)条（ d）点条所述两个日期中较晚日期后 18 个月起，废除第 93/42/EEC 号指令第 14(1)和(2)条以及第 14a(1)条第 (a)和(b)点自第 97(2)条和第 97(3)(ba)条，以及与器械和经济运营商注册有关的义务及相应附录中规定的证书通知。 Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation.

关于本法规第 120（3）和（ 4）条所述的器械，第一段所述的指令应继续适用，直至 2025 年 5 月 26 日适用于这些段落规定。 As regards the devices referred to in Article 120 (3) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

尽管有第一段规定，第 207/2012 号法规和第 722/2012 号法规仍生效，并继续适用，除非并直至委员会根据本法规通过的实施细则废除。 Notwithstanding the first paragraph, Regulations (EU) No 207/2012 and (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

应将废除的指令理解为对本法规的引用，并应按照本法规附录 XVII 中规定的对比表格进行阅读。 References to the

repealed Directives shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVII to this Regulation.

第 123 条

生效与应用日期 **Entry into force and date of application**

1. 本法规应在 《欧盟官方公报》 上公布后第 20 天生效。 This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. 自 2020 年 5 月 26 日起适用。 It shall apply from 26 May 2020.

3. 通过豁免第 2 段规定： By way of derogation from paragraph 2:

(a) 第 35 条至第 50 条自 2017 年 11 月 26 日起适用。但是，在 2020 年 5 月 26 日前，根据第 35 至 50 条规定所产生的公告机构义务应仅适用于根据第 38 条提交申请的机构； 本法规 Articles 35 to 50 shall apply from 26 November 2017. However, from that date until 26 May 2020, the obligations on notified bodies pursuant to Articles 35 to 50 shall apply only to those bodies which submit an application for designation in accordance with Article 38;

(b) 第 101 条和第 103 条自 2017 年 11 月 26 日起适用。 Articles 101 and 103 shall apply from 26 November 2017;

(c) 第 102 条自 2018 年 5 月 26 日起适用； Article 102 shall apply from 26 May 2018;

(d) 在不影响委员会根据第 34 条承担的义务情况下，由于在起草第 34（1）条所述计划时无法合理预见的情况，Eudamed 在 2020 年 5 月 26 日，与 Eudamed 有关的义务和要求应适用于第 34（3）条所述通知发布之日起六个月后的日期。上述句子所述的规定为： without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1), Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). The provisions referred to in the preceding sentence are:

- 第 29 条， Article 29,
- 第 31 条， Article 31,
- 第 32 条,
- 第 33(4)条,
- 第 40(2)条第二段,
- 第 42(10)条,
- 第 43(2)条,
- 第 44(12)条第二子段,
- 第 46(7)条(e)和(d)点,
- 第 53(2)条,
- 第 54(3)条,
- 第 70 至 77 条,
- 第 78 条第 1 至 13 段,

- 第 79 至 82 条,
- 第 86(2)条,
- 第 87 和 88 条,
- 第 89(5)和(7)条以及第 89(8)第三子段,
- 第 90 条,
- 第 93(4)、(7)和(8)条,
- 第 95(2)和(4)条,
- 第 97(2)最后一段,
- 第 99 (4)条,
- 第 120(3)第一子段第二句, the second sentence of the first subparagraph of Article 120(3).

在 Eudamed 全面运作之前，第 90/385/EEC 号指令和第 93/42/EEC 号指令的相应规定将继续适用于履行本点第一段关于信息交换条款中规定的义务，包括，特别是关于警戒报告、临床研究、器械和经济运营商的注册以及证书通知的信息。 Until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications.

(e) 第 29(4) 和第 56(5)条条应自第 （d）点所述日期起 18 个月后适用； Article 29(4) and Article 56(5) shall apply from 18 months after the later of the dates referred to in point (d);

(f) 对于可植入器械和 III 类器械，第 27(4)条应自 2021 年 5 月 26 日起适用。对于 IIa 和 IIb 类器械，第 27(4)条应自 2023 年 5 月 26 日起适用。对于 I 类器械，第 274(4)条应自 2025 年 5 月 26 日起适用；for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;

(g) 对于在器械本身带有 UDI 载体的可重复使用器械， 第 27(4)条应于该点规定相关类别器械段落 (f) 点所述之日起两年后适用； for reusable devices that shall bear the UDI carrier on the device itself, Article 27(4) shall apply from two years after the date referred to in point (f) of this paragraph for the respective class of devices in that point;

(h) 第 78 条规定程序应自 2027 年 5 月 26 日起适用，但不影响第 78（14）;The procedure set out in Article 78 shall apply from 26 May 2027, without prejudice to Article 78(14);

(i) 第 120(12)条应自 2019 年 5 月 26 日起适用。 Article 120(12) shall apply from 26 May 2019.

本法规应整体具有约束力，并直接适用于所有成员国。 This Regulation shall be binding in its entirety and directly applicable in all Member States.

于 2017 年 4 月 5 日签发 …… Done at Strasbourg, 5 April 2017

欧洲议会	理事会
会长	会长
A. TAJANI	I. BORG

附录 ANNEXES

附录 I ANNEX I

通用安全与性能要求 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

第 I 章 CHAPTER I

一般要求 GENERAL REQUIREMENTS

1. 器械应具备制造商预期的性能，并确保其设计和结构在正常使用条件下适用于其预期用途。器械应安全有效，且不得对患者的临床症状或安全或者使用者或其他人员（如适用）的安全和健康造成损害，在最大限度保护健康和安全的同时，器械使用的可接受风险与其对患者的益处相比，应在可接受范围内，并应考虑到符合现有认知水平。

   Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. 本附录中尽可能降低风险的要求指尽可能降低风险的同时不会对收益风险比产生不利影响。

   The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3. 制造商应建立、实施、记录和维护风险管理体系。Manufacturers shall establish, implement, document and maintain a risk management system.

   风险管理应理解为在器械整个生命周期中为连续迭代过程，需定期进行系统更新。进行风险管理制造商需做到：

   Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

   (a) 制定并记录各器械的风险管理计划； establish and document a risk management plan for each device;

   (b) 识别和分析与各器械相关的已知和可预见的危害； identify and analyse the known and foreseeable hazards associated with each device;

   (c) 估计和评价在预期使用时及在可合理预见的使用不当时产生的相关风险； estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

   (d) 根据第 4 节的要求消除或控制 (c)点所述的这些风险； eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

   (e) 评估生产阶段，特别是上市后监管体系的信息、危害及其发生频率、评估其相关风险及总体风险、风险利益比和风险可接受性。 evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

   (f) 根据 (e)点所述信息影响的评估，必要时根据第 4 节的要求修改控制措施。 based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. 制造商就器械的设计和制造所采取的风险控制措施应符合安全原则，并考虑到现有的技术水平。为降低风险，

制造商应对风险进行管理，使各危害相关的剩余风险及总剩余风险控制在可接受范围内。在选择最合适的解决方案时，制造商应依据下述优先级原则： Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

(a) 通过安全的设计和制造尽可能消除或降低风险； eliminate or reduce risks as far as possible through safe design and manufacture;

(b) 如适合，采取适当保护措施，关于无法消除的风险，包含必要时的报警；且 where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and

(c) 提供安全信息 （警戒 /预防措施 /禁忌），并在适当情况下向使用者提供培训。 provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

制造商应将剩余风险告知使用者。 Manufacturers shall inform users of any residual risks.

5. 在消除或减少使用不当相关风险时， 制造商应： In eliminating or reducing risks related to use error, the manufacturer shall:

(a) 尽量降低因器械人体工程学特点及其预期使用环境所造成的风险 （针对患者安全而设计） ，以及 reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

(b) 针对技术知识、经验、教育、培训和使用环境，以及预期使用者医疗及身体条件（如适用）的注意事项（针对非专业、 专业、残疾或其他使用者而设计） 。give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. 如器械在正常使用环境中使用并根据制造商的指示进行适当维护保养，在制造商声称的使用期限内器械的特性和性能不得对患者、 使用者或其他人员 （如适用） 的健康或安全造成损害。 The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. 器械的设计、制造和包装应确保在根据制造商提供的说明和信息进行运输和储存期间（如温度和湿度的波动） ，不会对器械在预期使用期间的特性和性能造成不利影响。 Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. 与正常使用条件下器械预期性能对患者和 /或使用者产生的潜在益处相比， 所有已知和可预见的风险及任何不良影响应最小化并控制在可接受范围内。 All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

9. 对于在附录 XVI 中所列出的，制造商未声称用于医疗目的之器械， 应充分了解在第 1 节和第 8 节规定的通用安全要求，即在预期条件下出于预期目的而使用器械时，器械不得出现任何风险，或出现不超过与产品使用相关的最大可接受风险， 这符合高水平保障人员安全和健康原则一致。 For the devices referred to in Annex XVI, the

general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

第 II 章
设计和生产相关要求
REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

10. 化学、物理和生物学特性 Chemical, physical and biological properties

10.1. 器械的设计和生产应当能确保符合第 I 章中所述的特性和性能要求。 特别注意： Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:

(a) 使用材料和物质的选择，特别是毒性和易燃性（如适用） the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;

(b) 所使用材料和物质与生物组织，细胞及体液间的相容性，及考虑到器械使用目的及相关的吸收、分布、新陈代谢和排泄； the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;

(c) 器械不同部件之间的兼容性， 该器械由多个可植入部件组成； the compatibility between the different parts of a device which consists of more than one implantable part;

(d) 过程对材料性能的影响； the impact of processes on material properties;

(e) 如适用，生物物理学或建模研究结果有效性已事先获得证实； where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;

(f) 所使用材料的机械性能，在适当情况下反映诸如强度、延展性、抗断裂性、耐磨性和耐疲劳强度等问题； the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;

(g) 表面活性； surface properties; and

(h) 确认该器械满足任何确定的化学和 /或物理要求。 the confirmation that the device meets any defined chemical and/or physical specifications.

10.2. 器械的设计、生产和包装应尽可能降低污染物和残留物对患者造成的风险，同时考虑到器械预期用途以及参与器械运输、储存和使用的人员。 Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices.

应当特别注意暴露于这些污染物和残留物的组织以及暴露时间与频率。

Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. 器械的设计和生产应以能使其可安全地与材料和物质（包括气体）一起使用，且在预期使用时，这些材料和物质会与器械接触；若器械预期用于管理医疗产品，根据管理这些医疗产品的条款和限制，则其设计和制造应使其能够与相关的医疗产品兼容，并应可根据其相应的指示和预期用途维护医疗产品和器械的性能。 Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.

10.4. 物质 Substances

10.4.1 器械的设计和生产 Design and manufacture of devices

器械的设计和制造应尽可能降低由物质或颗粒（包括磨屑、降解产物和加工残留物）造成的风险，而此类物质或颗粒可能由器械产生。 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

器械或其部件或其使用的材料： Devices, or those parts thereof or those materials used therein that:

- 具有侵入性，并与人体直接接触，或 are invasive and come into direct contact with the human body,
- （重新）为人体输送药物、体液或其他物质（包括气体），或 (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- 运输或储存待（重新）为人体输送药物、体液或物质（包括气体），transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,

在根据第 10.4.2 节进行调整时，应仅包含浓度高于 0.1% 重量比的以下物质： shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

(a) 1A 或 1B 类有致癌、致突变或生育毒性 ('CMR') 的物质，依据欧洲议会和理事会第 1272/2008 号法规附录 VI 第 3 部分判断，或 substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or

(b) 有科学证据证明可能对人类健康造成严重影响的具有内分泌干扰性质的物质，根据欧洲议会和理事会第 1907/2006 号法规（[2]）第 59 条规定程序识别，或者委员会根据欧洲议会和理事会第 528/2012 号法规（[3]）第 5（3）条第一段通过授权法案后，根据本法规规定之与人类健康相关准则识别。 substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.

10.4.2. 关于存在 CMR 和/或内分泌干扰物的理由，存在此类物质的理由应基于： Justification regarding the presence of CMR and/or endocrine-disrupting substances The justification for the presence of such substances shall be based upon:

(a) 对潜在患者或使用者暴露于该物质下情况进行分析和判断； an analysis and estimation of potential patient or user exposure to the substance;

(b) 对可能的替代物质、材料或设计进行的分析，（在可用时）包括有关独立研究、同等评审研究、相关科学委员会的科学意见等信息，以及对这些替代品可用性的分析； an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;

(c) 论证可能的物质和/或材料替代品（如有）或设计变更（如可行）不适用于维护产品功能、性能和利益

-风险比的原因；包括要考虑这些器械的预期用途是否包括儿童治疗，或孕妇或哺乳妇女治疗，或对其他特别容易受到此类物质和 /或材料影响的患者群体的治疗； argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and

(d) 如适用和可用时，基于根据第 10.4.3 节和 10.4.4.节制定的最新相关的科学委员会指南。 where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4

10.4.3. 邻苯二甲酸酯使用指南 Guidelines on phthalates

为达到该附录第 10.4 节的目的，委员会应尽快并于 2018 年 5 月 26 日向相关科学委员会提供任务以制定指南，且该指南应在 2020 年 5 月 26 日前编制好。 委员会的任务至少应包含对邻苯二甲酸酯存在的利益风险评估，其中邻苯二甲酸酯属于第 10.4.1 节要点（ a）和（ b）中所所述物质组中的任何一组。利益风险评估应考虑器械、可用替代物质和替代材料、设计和 /或药物治疗使用的预期目的和环境。虽然根据最新科学证据认为是适当的，但应至少每五年更新一次该指南。 For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.

（**1**）欧洲议会和理事会于 2008 年 12 月 16 日签发的关于物质和混合物分类、 标签和包装的第 1272/2008 号法规，修订和废除第 67/548/EEC 号指令和第 1999/45/EC 号指令，并修订了第 1907/2006 号法规（ OJ L 353, 31.12.2008, p. 1）。

（**2**）欧洲议会和理事会于 2006 年 12 月 18 日签发的关于化学品注册、 评估、授权和限制（REACH ）的第 1907/2006 号法规（OJ L 396,30.12.2006, p. 1）。

（**3**）欧洲议会和理事会于 2012 年 5 月 22 日签发的关于在市场上提供和使用杀生物产品的第 528/2012 号法规 （OJ L 167，27.06.2012,p. 1）。

10.4.4. 其他 CMR 和内分泌干扰物质的指南 Guidelines on other CMR and endocrine-disrupting substances

随后，委员会应委任相关科学委员会按照第 107.4.3 中所述的要求，也为第 10.4.1 节要点（ a）和（ b）中所所述的其他物质制定指南。 Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.

10.4.5 贴标 Labelling

按照第 10.4.1 节所述的要求， 若此中所使用的器械、 其部件或材料， 包含第 10.4.1 节中所述的浓度高于 0.1% 重量比的物质， 则应在器械本身和 /或各单元的包装上或， （适当时） 在销售包装上把此类物质清单标记清楚。 若此类器械的预期用途，包括儿童治疗，或孕妇或哺乳妇女治疗，或对视为特别易受到此类物质和 /或材料影响的其他患者群体的治疗，则关于这些患者群体的残余风险、 （如适用）预防措施信息，均应在使用说明中给出。 Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.

10.5. 必须合理设计及生产器械，以尽量降低因物质意外进入器械而造成的风险，并且应考虑到器械及其预期使用环境的性质。 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

10.6. 器械的设计和制造应尽可能减少与颗粒尺寸和性能相关的风险，除非这些颗粒接触到的是完好的皮肤，否则这些颗粒会位于或可释放到患者或使用者体内。应特别注意纳米材料。 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.

11. 感染及微生物污染 Infection and microbial contamination

11.1. 器械和制造过程的设计应尽可能消除或减少感染患者、 使用者和（适用时） 其他人的风险。 设计应：Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

(a) 尽可能减少并消除意外由于切割和刺破造成的风险， 例如针刺损伤， reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,

(b) 使用便捷安全， allow easy and safe handling,

(c) 尽可能降低器械的微生物泄漏和 /或使用过程中的微生物暴露， reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and

(d) 防止器械或其所包含之物 （例如样本或液体） 受到微生物的污染。 prevent microbial contamination of the device or its content such as specimens or fluids.

11.2 必要时，应将器械设计成便于进行安全清洁、消毒和 /或再灭菌。 Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.

11.3. 应对标记为具有特殊微生物种群的器械进行设计、制造和包装，以确保在投放到市场时，及在制造商规定的运输和储存条件下，器械依旧保持原样。 Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

11.4 应根据适当流程，对在无菌状态下运输的器械进行设计、制造和包装，以确保在投放到市场时，及在制造商指定的运输和储存条件下，器械能保持无菌状态，除非旨在保持其无菌状态的包装遭到损坏，仍保持无菌，直至保护包装破损或出于使用目的而打开时。这些措施应确保最终使用者可清晰可见无菌包装的完整性。 Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

11.5. 应通过适当的经过验证的方法处理、制造、包装和灭菌标记为无菌器械。 Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

11.6. 用于灭菌的器械应采用适当且可控条件和设备进行制造和包装。 Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.

11.7. 若器械在使用前灭菌，则非无菌器械的包装系统应保持产品的完整性和清洁度，以尽量减少微生物污染风险；此外，包装系统应适当考虑制造商指定的灭菌方法。 Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

11.8. 器械标识除带有灭菌产品的指示符号外，还应可区别市场上相同或相似器械的灭菌和非灭菌状态。 The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

12. 包含被认为是医药产品物质的器械，及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械 Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

12.1. 对于第 1(8)条第一子段所指的器械，若单独使用，则该物质的质量、安全性和可用性将被视为是符合第 2001/83/EC 号指令第 1 条(2)点的医药产品，则应按照本法规中适用的符合性评估流程的规定，使用与第 2001/83/EC 号指令附录 I 所规定方法相似的方法进行验证。 In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.

12.2. 预期植入到人体，以及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械， 应遵从，（适用时）并受限于本法规与第 2001/83/EC 号指令附录 I 中规定的相关要求未涵盖方面，而这些相关要求用于按照本法规适用的符合性评估流程，对吸收、分配、新陈代谢、排泄、局部耐受性、毒性，与其他器械、医药产品呼呼其他物

质和相互影响，及副作用的潜在影响进行评估。 Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.

13. 包含生物来源材料的器械 Devices incorporating materials of biological origin

13.1. 对于使用由本法规涵盖的非活性或处理为非活性人源生物组织或细胞制造成的器械，根据第 1(6)条(g)点，适用以下规定： For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:

(a) 对用于器械生产的人源组织和细胞的捐赠、购买和测试应根据第 2004/23/EC 号指令完成。 donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;

(b) 应对那些组织和细胞或其衍生物进行处理、保存和任何其他操作，从而为患者、使用者、（适用时）其他人员提供安全保障。特别是，应通过适当的来源方法，以及通过在制造过程中实施经验证的消除或失活方法处理与病毒和传染因子安全性相关的问题。 processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;

(c) 这些器械的可追溯体系应与第 2004/23/EC 号指令和第 2002/98/EC 号指令所规定可溯源性和数据保护要求是互补和相兼容。 the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.

13.2. 对于使用非活性或处理非活性动物源组织或细胞，或其衍生物制造的器械，应适用以下规定： For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply:

(a) 在可行的情况下，考虑到动物物种，动物源组织和细胞或其衍生物应来自已经受兽医控制，即适合于组织预期使用的动物。由制造商保留动物地理来源信息。 where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers;

(b) 应获取动物源组织、细胞和物质或其衍生物，并对其进行处理、保存、测试和操作，从而为患者、使用者和其他人员（如适用）提供安全保障。特别是关于病毒和其他传播因子的安全性，应通过在制造过程中，实施经验证的消除或病毒灭活方法来解决，除非此类方法的使用会导致不可接受的降解，损害器械的临床益处。 sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;

(c) 在使用动物来源的组织或细胞或其衍生物制造的器械，如第 722/2012 号法规所述，应适用该法规规定的特别要求。 in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.

13.3. 对于使用其他非活性生物物质制造的器械， 在第 13.1 和 13.2 节所述的情况下， 应对这些物质的进行加工、 保存、测定和处理，以便为患者、使用者和其他人（如适用）提供安全性，包括整条废物处理链。特别是，应通过适当的来源方法，及通过在生产过程中实施经验证的消除或失活方法处理与病毒和传染因子安全性相关的问题。

For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

14. 器械构造及其与环境之间的相互作用

Construction of devices and interaction with their environment

14.1. 若器械预定与其他器械或设备一起配合使用，必须保证整个系统（包括连接系统）具有安全性，同时不得改变本器械的指定性能。此类组合结构的任何使用限制应在标签和 /或使用说明书上标明。应以尽量减少所有可能的风险（如误连接）的方式设计和构造使用者必须处理的连接件，例如流体、气体输送、电气或机械联轴节。

If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.

14.2. 应采用适当方式设计和制造器械，确保尽可能地避免或减少以下内容： Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:

(a) 与器械物理特征有关的伤害风险， 包含体积 /压力比、 尺寸、 和人体工程学特征 （如适用）；the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;

(b) 与可合理预见的外部影响或环境条件相关的风险，例如磁场、外部电场和电磁效应、静电放电、诊断或治疗过程的辐射、压力、湿度、温度、压力变化和压力加速或者无线电信号干扰； risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(c) 与该器械使用相关的风险， 当其接触材料、 液体和物质时， 包括其在正常使用条件下暴露接触的气体； the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(d) 与软件和 IT 环境间的可能负相互作用相关的风险，器械在该 IT 环境内操作和相互作用； the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;

(e) 物质意外进入器械的风险； the risks of accidental ingress of substances into the device;

(f) 在研究中正常使用或给予治疗期间，与其他器械相互干扰造成的风险； the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and

(g) 由于下面原因导致的风险：材料老化、测试或控制机能精准度下降而无法维修或校正（如植入人体后）器械。 risks arising where maintenance or calibration are not possible (as with implants), from ageing of

materials used or loss of accuracy of any measuring or control mechanism.

14.3. 必须适当地设计和制造器械，确保在正常使用期间和单一故障情形下尽量减少火灾或爆炸风险。应特别留意此类器械：其预期用途包括暴露于或与易燃易爆物质或可引燃物质结合使用的器械。 Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

14.4. 器械的设计和制造应确保可安全且有效地进行调整、 校准和维护。 Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

14.5. 用于与其他器械或产品协同操作的器械设计和制造应确保其互通性和兼容性可靠且安全。 Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

14.6. 应根据人体工程学原理设计和制造任何测量、监测或显示器标度的器械，且考虑到器械的预期用途、使用者以及器械预期使用所在的环境条件。 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

14.7. 应以此类方式设计和制造器械，以便于使用者、患者或其他人安全处置器械和 /或相关废物。为此，制造商应研究并测试程序和措施， 以便器械使用后可安全处置。 这些程序应在使用说明中给出。 Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.

15. 具有诊断或测定功能的器械

Devices with a diagnostic or measuring function

15.1. 应以此类方式设计和制造具有测定功能的诊断器械和器械，应根据适当的科学和技术方法为其预期用途提供足够的准确度、精度和稳定性。准确度范围应由制造商指定。 Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.

15.2. 具有监测功能的器械进行并且以合法单位表示的测量应符合理事会第 80/181/EEC 号指令关于成员国对于测量单位的相似法律以及废除第 71/354/EEC 号指令（ [1]）的规定。 The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (4).

([1]) 1979 年 12 月 20 日关于成员国关于衡量单位法律的理事会第 80/181/EEC 号指令，并废除第 71/354/EEC 号指令。(OJ L 39, 15.2.1980, p. 40)

16. 辐射防护 Protection against radiation

16.1. 总论 General

(a) 必须适当地设计、制造和包装器械，确保在预定用途下尽量减少对患者、使用者和其他人员造成辐射，但在治疗和诊断目的使用下不对规定合理的剂量进行限制。 Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(b) 发出有害或潜在危险辐射的器械的操作说明应包含关于发射辐射性质、保护患者和使用者的方法，以及避免误用和尽可能和适当减少安装固有风险的详细信息。此外，还应指定有关验收试验、性能试验、验

收标准以及维修保养程序的信息。 The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

16.2. 预期辐射 Intended radiation

(a) 若器械因实现特定医疗目的而不可避免地辐射危害或潜在危害水平的电离和 /或非电离辐射，并且其收益一般视为超过该辐射内固有的风险，则使用者必须可控制辐射。此类器械的设计和制造应确保相关可变参数在可接受公差范围内的再现性。 Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

(b) 当器械用于发射有害或潜在危险的电离和 /或非电离辐射时， 应尽可能安装此类发射的可视显示器和 /或声响报警信号。 Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

16.3. 应采用适当方式设计和制造器械，确保尽可能降低患者、使用者和其他人员遭受非预期、漫辐射或散射辐射暴露。在可能和适当的情况下，应选择减少患者、使用者和可能受影响的其他人的辐射暴露方法。 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

16.4. 电离辐射 Ionising radiation

(a) 旨在发射电离辐射的器械的设计和制造应考虑到第 2013/59/Euratom 号指令的要求， 其中规定了防止由于暴露于电离辐射而产生危险的基本安全标准。 Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

(b) 旨在发射电离辐射的器械的设计和制造应确保（如可能）考虑到可在治疗期间改变和控制和（如可能）监测所发射辐射的预期用途、 数量、几何形状和质量。 Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment.

(c) 若会发射离子辐射的器械预定用于放射医学诊断，则应采用适当方式设计和制造器械，确保获得符合预期医疗用途的合适图像和 /或输出质量，同时尽量减少对患者和使用者的辐射。 Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user.

(d) 若会发射离子并预定用于放射医治的器械，则应采用适当方式设计和制造器械，确保可监控和控制器械

辐射剂量、光束类型和能量以及辐射质量（如适用）。Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.

17. 可编程电子系统 —— 包含可编程电子系统的器械与本身就是器械的软件

Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1. 包含可编程电子系统（包括软件）的器械或者自身为器械的软件，其设计应根据其预期用途确保相应可重复性、可靠性和性能。在单一故障条件下，应采取适当手段以尽可能消除或降低由此造成的风险或性能损害。

Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

17.2. 针对包含软件的器械或自身为器械的软件，应根据现有技术开发和制造软件，同时考虑开发生命周期原则、风险管理，包括信息安全、验证和确认。

For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

17.3. 本节所指软件用于与移动计算平台结合使用，其设计和制作应考虑移动平台的具体特征（如，屏幕的大小和对比度）以及与其用途相关的外部因素（环境变化，如光照或噪声水平）。Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

17.4 制造商应规定有关硬件、IT 网络特性和 IT 安全措施的最低要求，包括防止非授权访问、按预期运行软件的必要条件。Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

18. 有源器械和与其连接的器械

Active devices and devices connected to them

18.1. 对于非植入式有源器械，在出现单一故障情况时，应采取适当的措施尽可能消除或减少由此产生的风险。For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.

18.2. 当患者的安全性取决于内部电源时，此类器械应配备可确定电源状态的手段，并且当电源容量处于临界值时。必要时应在电源容量变为临界值之前，提供适当警告或指示。Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.

18.3. 若患者安全取决于外部供电，器械必须包含一个报警系统，用于指示任何电力故障。Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.

18.4. 若器械预定用于监测患者内一个或多个临床参数，器械必须配备适当报警系统，用于提供有关可导致患者死亡

或健康状态严重恶化的警戒信息给使用者。 Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

18.5. 器械的设计和制造应尽可能降低产生电磁干扰的风险，以免影响相关器械或该使用环境下其他器械或设备的操作。 Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

18.6. 器械的设计和制造应提供充足的抗电磁干扰天然免疫水平，使其足以使器械按预期操作。 Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

18.7. 器械的设计和制造应尽可能避免在正常使用器械期间和在单一故障情况下对患者、使用者或任何其他人造成意外电击危险， 但前提是器械须按照制造商的指示安装和维护保养。 Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

18.8. 器械的设计和制造应尽可能保护对器械的未经授权访问，以免器械无法正常运行。 Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.

19. 有源可植入器械的特殊要求 Particular requirements for active implantable devices

19.1. 应采用适当方式设计和制造有源可植入器械，确保尽可能地避免或减少： Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible:

(a) 根据特定参考文献，与使用能源相关的风险，如使用电力，器械的绝缘、漏泄电流和过热风险， risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,

(b) 与医疗有关的风险， 特别是使用除颤器或高频外科手术器械产生的风险， risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment, and

(c) 在不可能进行维护和校准时可能出现的风险，包括： risks which may arise where maintenance and calibration are impossible, including:

- 漏泄电流过度增大， excessive increase of leakage currents,
- 所使用材料的老化， ageing of the materials used,
- 器械产生的过热， excess heat generated by the device,
- 测量或控制机制准确性降低。 decreased accuracy of any measuring or control mechanism.

19.2. 有源可植入器械的设计和制造应确保 Active implantable devices shall be designed and manufactured in such a way as to ensure

- 如适当，器械与其预期施用物质的兼容性， if applicable, the compatibility of the devices with the substances they are intended to administer, and
- 能源的可靠性。 the reliability of the source of energy.

19.3. 有源可植入器械（如适当）及其组成部分应可识别，以便允许在发现与器械或其组成部分相关的潜在风险之后采取任何必要的措施。 Active implantable devices and, if appropriate, their component parts shall be identifiable to

allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.

19.4. 有源可植入器械应附带可明确识别自身及其制造商的代码（特别是关于器械的类型和制造年份）；若必要，应可读取该代码，而不需要进行外科手术。 Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.

20. 机械和热风险防护 Protection against mechanical and thermal risks

20.1. 应采用适当方式设计和制造器械，确保防止患者和使用者遭受与机械特征有关的机械风险，例如：运动阻力、稳定性或运动部件等。 Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

20.2. 应采用适当方式设计和制造器械，确保尽量降低因器械振动引起的风险水平，并考虑利用先进技术和手段限制振动（尤其振动源处），除非振动是规定性能中一部分。 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

20.3. 应采用适当方式设计和制造器械，确保尽量降低因噪音释放而产生的风险水平，并考虑利用先进技术和手段减少噪音（尤其噪音源处），除非这种噪音是规定性能中组成部分。 Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

20.4. 若使用者或他人必须操作连接到电力、气体、液压或气动能量供给源的端子和连接器，应采用适当方式设计和构造此类端子和连接器，确保尽量降低任何潜在风险。 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.

20.5. 当安装或重装某些部件时可能出现的失误将有可能成为风险的源头，此类部件的设计和构造应完全避免该风险，若无法实现，则应通过在部件和/或其外壳的信息说明。 Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

当需要知道移动方向以避免风险，相同信息应在活动部件和/或其外壳说明。 The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk

20.6. 在正常使用条件下，器械内可接触部件（不包括拟供热或达到给定温度的部件或区域）及其周围可触及部件不会达到造成危险的温度。 Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

21. 通过器械供应能量或物质防止对患者或使用者造成危险

Protection against the risks posed to the patient or user by devices supplying energy or substances

21.1. 若器械预定用于为患者供给能量或物质，应采用适当方式设计和制造器械，确保能够准确地设置和维持输送量，从而足以保证患者和使用者的安全。Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.

21.2. 器械应配备防止和/或指示输送可能产生危险的能量或物质数量方面的任何不足。器械必须集成适当手段，确保尽可能地防止危险等级的能源或物质从能源及/或物质来源中泄漏。Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

21.3. 控制器和指示器功能必须明确地注明在器械上。若器械提供使用说明或者通过一个可视系统指示操作或调整参数，必须保证使用者和患者（如适用）易于理解这些信息。The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.

22. 防止制造商预期用于非专业人员使用的医疗器械所造成的危险 Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

22.1. 由非专业人员使用的器械的设计和制造应使其适用于预期用途，其中考虑到可用于专业人员的技能和方法以及在非专业人员的技术和环境中合理预期差异导致的影响。制造商提供的信息和说明应易于非专业人员理解和应用。 Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

22.2. 由非专业人员使用的器械的设计和制造应： Devices for use by lay persons shall be designed and manufactured in such a way as to:

- 确保目标使用者在适当训练和/或信息获得后的所有必要治疗阶段均可安全且准确使用器械；和 ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,
- 尽可能减少并消除意外由于切割和刺破造成的风险，例如针刺损伤；和 reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and
- 尽可能减少预期使用者在处理器械以及（如适当）在结果解读中的错误风险。 reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

22.3. 由非专业人员使用的器械（如适当）应包括非专业人员使用的规程 Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:

- 在使用时，可验证器械将按照制造商的意图工作，并且 can verify that, at the time of use, the device will perform as intended by the manufacturer, and
- 如适当，若器械未能提供有效的结果，则发出警告。 if applicable, is warned if the device has failed to provide a valid result.

第 **III** 章.

有关器械随附信息的要求

REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

23. 标签和使用说明书 **Label and instructions for use**

23.1. 制造商需提供的信息的一般要求

General requirements regarding the information supplied by the manufacturer

各器械应附有识别器械及其制造商所需的信息，并酌情将安全与性能信息传达给使用者或其他人。此类信息可能出现在器械本身、包装上或使用说明书中，若制造商有网站，则应在网站上提供并保持更新最新信息，同时考虑到以下因素： Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

(a) 标签和使用说明的介质、格式、内容、易读性和位置应适合于特定器械、其预期目的和对预期使用者的技术知识、经验、教育或培训。尤其是，使用说明书应以预期使用者容易理解的语言撰写，并且在适当时，补充图纸和图表。 The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.

(b) 标签上所需的信息应在器械本身上提供。若不可行或不适当，则某些或所有信息可显示在各单元的包装上和 /或多个器械的包装上。 The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

在向单个使用者和 /或位置提供多个器械的情况下，若购买者如此同意，则可提供使用说明的单个副本，在任何情况下购买者可请求免费提供进一步的副本。

(c) 标签应以人类可读的格式提供， 并可通过机器可读信息， 例如射频识别 （“ RFID ”）或条形码来补充。 Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio- frequency identification (‘ RFID ’) or bar codes.

(d) 使用说明应与器械一起提供。例外情形：对于 I 类和 IIa 类器械，若在无使用说明书的情形下同样可安全地使用器械， 则无需此类使用说明书。 除非本节其他地方另有规定。 Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.

(e) 当向单个使用者和 /或位置提供多个器械时，若购买者同意，则可提供使用说明的单个副本，但购买者在任何情况下可请求免费提供其他副本。 Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

(f) 若根据第 207/2012 号法规或根据本法规通过的任何后续实施规则中规定的条件，可向使用者提供非纸质格式（例如， 电子格式） 使用说明。。Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.

(g) 需要传达给使用者和 /或其他人的剩余风险应包括作为制造商所提供信息中的限制、禁忌症、预防措施或警戒。 Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.

(h) 如适当，制造商提供的信息应采用国际公认的符号形式。使用的任何符号或识别颜色应符合协调标准或 CS。若未协调标准或 CS，符号和颜色应说明在随同器械提供的文件中。 Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

23.2. 标签上的信息 Information on the label

标签必须注明下面全部事项： The label shall bear all of the following particulars:

(a) 器械的名称或商品名称； the name or trade name of the device;

(b) 使用者识别器械所必需的详细信息、 包装内容以及对于使用者不明显的器械预期用途； the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;

(c) 制造商的名称、注册商号或注册商标及其注册营业地点的地址； the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;

(d) 授权代表的姓名和授权代表的注册营业地点地址（若制造商在欧盟以外有其注册营业地点） ；if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;

(e) 如适当，器械包含或采用的指示信息， where applicable, an indication that the device contains or incorporates:

- 药物，包括人血或血浆衍生物或 a medicinal substance, including a human blood or plasma derivative, or
- 人源的组织或细胞或其衍生物或 tissues or cells, or their derivatives, of human origin, or
- 动物源的组织或细胞或其衍生物， 如第 722/2012 号法规所述。 tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;

(f) 如适当，标签信息应符合第 10.4.5 节规定； where applicable, information labelled in accordance with Section 10.4.5.;

(g) 批号或前面带有词语 LOTNUMBER 或 SERIAL NUMBER 的器械的序列号或等效符号（如适用） ；the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

(h) 根据第 27(4)条和附录 VII 第 C 部分的 UDI ；the UDI carrier referred to in Article 27(4) and Part C of Annex VII;

(i) 明确指示可安全使用或植入器械的时间限制，至少表示为与之相关的年份和月份； an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;

(j) 若没有指明可安全使用的日期，则指明制造日期。若日期清晰可辨，制造日期可作为批号或序列号的一部分。 where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

(k) 指明适用的任何特殊储存和 /或处理条件； an indication of any special storage and/or handling condition that applies;

(l) 若以无菌方式提供器械，还应指示其无菌状态和灭菌方法； if the device is supplied sterile, an indication of its sterile state and the sterilisation method;

(m) 需要立即引起器械使用者和任何其他人的注意、需要采取的警戒或预防措施。该信息可保持最小量，在这种情况下， 更详细的信息将出现在使用说明中， 同时考虑到预期使用者； warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;

(n) 若器械用于一次性使用， 则相应指明。 制造商的一次性使用指示应在整个欧盟内保持一致； if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;

(o) 若器械是已进行再处理的一次性使用器械，提供该事实的指示信息、已执行的再处理循环次数以及关于再处理循环次数的任何限制； if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;

(p) 若器械是定制的， 则提供词语“ 定制器械 ” ;if the device is custom-made, the words ‘ custom-made device

(q) 一项指示信息，用于指示器械为医疗器械。若本器械仅预定用于临床研究，应标明“ 临床研究专用 ” ；an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘ exclusively for clinical investigation ’;

(r) 若器械包含预计经由身体孔口引入人体或施加在皮肤上，并被人体吸收或局部喷洒在人体上的物质或物质组合，则提供器械的整体定量成分和负责实现主要预期作用的主要成分的定量信息； in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;

(s) 对于有源可植入器械，提供序列号，对于其他可植入器械，提供序列号或批号。 for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.

23.3. .关于保持器械无菌条件的包装信息（ “ 无菌包装 ”）： Information on the packaging which maintains the sterile condition of a device (‘ sterile packaging ’）

无菌包装上应出现以下细节： The following particulars shall appear on the sterile packaging:

(a) 指明无菌包装标识， an indication permitting the sterile packaging to be recognised as such,

(b) 声明该器械处于无菌状态， a declaration that the device is in a sterile condition,

(c) 灭菌方法， the method of sterilisation,

(d) 制造商名称和地址， the name and address of the manufacturer,

(e) 器械说明， a description of the device,

(f) 若本器械仅预定用于临床研究，应标明“ 临床研究专用 ” ， if the device is intended for clinical investigations, the words ‘ exclusively for clinical investigations ’,

(g) 若属于定制器械，应标明“ 定制器械 ” ， if the device is custom- made, the words ‘ custom-made device ’,

(h) 制造月份和年份， the month and year of manufacture,

(i) 安全使用或植入器械的时间限制的明确指示信息，并表示为与之相关的年份和月份； an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and

(j) 检查使用说明的说明，即若无菌包装损坏或在使用前不小心打开，该如何处理。 an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

23.4. 使用说明书中的信息 Information in the instructions for use

使用说明应包含以下全部详细规定： The instructions for use shall contain all of the following particulars:

(a) 第 23.2 节第（ a）、（c）、（e）、（f）、（ k）、（l）、（n）和（ r）点所述的详细规定； the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;

(b) 器械的预期用途具有适应症、禁忌症、患者目标群体和预期使用者（如适用）的明确规范； the device's

intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;

(c) 如适用，提供预期的临床收益规范； where applicable, a specification of the clinical benefits to be expected.

(d) 如适用， 提供按照第 32 条的安全和临床性能总结链接； where applicable, links to the summary of safety and clinical performance referred to in Article 32;

(e) 器械的性能特征； the performance characteristics of the device;

(f) 如适用，提供信息用于医疗保健专业人员验证器械是否合适， 并选择相应的软件和附录； where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;

(g) 任何剩余风险、禁忌症和任何不良副作用，包括传达给患者的关于这方面的信息； any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;

(h) 使用者适当地使用器械的要求规范， 例如， 若器械具有测定功能， 提供其所要求的准确度； specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;

(i) 在准备使用之前或在其使用（例如，灭菌、最终组装、校准等）期间器械的任何预处理或处理的细节，包括确保患者安全所需的消毒水平和实现那些消毒水平所需的所有可用方法； details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;

(j) 所有特殊设施的任何要求或特殊培训或器械使用者和 /或其他人的特定资格； any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;

(k) 验证器械是否正确安装并是否准备好安全以及按制造商意图执行的信息 （若相关）：the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- 预防和定期维护以及任何预备清洁或消毒的性质和频率的详细信息； details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,
- 任何消耗部件的标识和更换方法； identification of any consumable components and how to replace them,
- 任何必要的校准信息，其用以确保器械在其预期寿命期间正常和安全地工作； information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and
- 消除参与安装、校准或维修器械的人所遇到风险的方法。 methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;

(l) 若提供的器械是无菌的，则无菌包装在使用前被损坏或无意打开的情况下，应提供说明。 if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;

(m) 若提供的器械是非无菌的， 并且需要在使用前进行灭菌， 应提供适当的灭菌说明。 if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;

(n) 若器械可重复使用，提供重复必需的适当处理过程的相关信息，包括清洁、消毒、包装以及（如适当）

经过验证的适用于器械投放市场所在成员国的重新灭菌方法。 应提供信息以识别该器械何时不得再使用，例如，材料劣化迹象或允许重复使用的最大数量。 if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses

（o）必要的指示信息， 指示只有在制造商负责进行重新调整后符合通用安全与性能要求， 方可重复使用该器械。 an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;

(p) 若器械带有一次性使用指示，在重复使用器械的情形下，制造商已知的特性和技术因素相关信息可能会构成风险。此信息应基于制造商风险管理文档的特定部分，应详细说明这些特征和技术因素。若按照第23.1 节(d)点无需任何使用说明， 该信息必须按要求提供给使用者。 if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;

(q) 对于旨在与其他器械和 /或通用设备一起使用的器械： for devices intended for use together with other devices and/or general purpose equipment:

- 信息用于识别这些器械或设备，以便获得安全组合，和 /或 information to identify such devices or equipment, in order to obtain a safe combination, and/or
- 有关器械和设备组合的任何已知限制的信息。 information on any known restrictions to combinations of devices and equipment;

(r) 若器械发出辐射用于医疗用途： if the device emits radiation for medical purposes:

- 关于发出辐射的性质、类型和（如适当）强度和分布的详细信息； detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation,
- 防止患者、使用者或其他人在使用器械期间受到意外辐射的方法。 the means of protecting the patient, user, or other person from unintended radiation during use of the device;

(s) 有关允许向使用者和 /或患者通知任何警戒、预防措施、禁忌症、待采取措施以及与器械有关的使用限制信息。在相关情况下，此信息应允许使用者向患者简述所有警戒、预防措施、禁忌症、待采取措施以及与器械有关的使用限制。该信息应酌情包括： information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:

- 器械发生故障或可能会影响安全的性能变化时的警戒、预防措施和 /或待采取措施； warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,
- 警戒、预防措施和 /或就暴露于合理可预见的外部影响或环境条件采取的措施（例如磁场、外部电和电磁效应、 静电放电、 与诊断或治疗过程相关的辐射、 压力、湿度、或温度； warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and

electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

- 在特定诊断研究、评估或治疗处理或其他程序（例如，由影响其他设备的器械所发出的电磁干扰）期间，器械的合理可预见存在所造成的干扰风险的警戒、预防措施和/或待采取措施； warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

- 若器械用于管理人或动物来源的生物物质药品、组织或细胞或其衍生物，则在选择交付物质时需考虑任何可能的限制或不相容性； if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered

- 结合到器械中作为器械组成部分的药物或生物材料相关的警戒、预防措施和/或限制； warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and

- 与纳入器械的 CMR 或具有内分泌干扰性质或可能导致患者或使用者的致敏或过敏反应的材料相关的预防措施； precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;

(t) 若拟引入人体并由人体吸收或局部扩散在人体内的物质或物质组合构成，则该器械及其代谢产物产品与其他器械、药品和其他物质间相互作用的一般概况以及禁忌、不良副作用和过量风险的警戒和预防措施（如适用）。 in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;

(u) 对于可植入器械，有关患者可暴露材料和物质的总体定性和定量信息。 in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;

(v) 为便于安全处理器械、其附录和与其一起使用的耗材（如有），应采取的警戒或预防措施。该信息应酌情包括： warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate:

- 感染或微生物危害（例如，被人源潜在感染性物质污染的外植体、针或手术器械）； infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

- 物理性危害（例如来自尖锐物）。 physical hazards such as from sharps.

若可按照第 23.1 节（d）点要求无使用说明，则应根据要求将这些信息提供给使用者； If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;

(w) 对于非专业人员使用的器械，使用者应咨询医护专业人员。 for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional

(x) 对于根据本法规第 1(2)条涵盖的器械，关于缺乏临床收益以及与器械使用相关的风险信息。 for the devices

covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;

(y) 使用说明的发布日期, 若已修订, 最新版本使用说明的发布日期和标识符。 date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

(z) 向使用者和/或患者发出关于与器械有关的任何严重事件的通知, 应报告给使用者和/或患者所在成员国的制造商和主管机构。 a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

(aa) 根据第 18 条向患者提供有关植入器械的信息。 information to be supplied to the patient with an implanted device in accordance with Article 18;

(ab) 对于结合可编程电子系统的器械，包括软件或器械本身是软件，有关硬件、IT 网络特性和 IT 安全措施的最低要求（包括防止未经授权的访问） 对于运行软件来说所必要的。 for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

附录 II

技术文件 TECHNICAL DOCUMENTATION

如适用，制造商应以清晰、有组织、易于检索和表达明确的方式提出其编制的技术文件及其总结，并应特别包括本附录中所述的以下要素： The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

1. 器械说明与性能指标，包括变型和附件 DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. 器械说明与性能指标 Device description and specification

(a) 产品或商品名和器械的一般说明，包括其预期目的和预期使用者； product or trade name and a general description of the device including its intended purpose and intended users;

(b) 在附录 VI 第 C 部分中所述的制造商对所讨论器械归结的基本 UDI-DI，只要该器械的标识应基于 UDI 系统，或依靠产品代码、目录编号或其他可追溯的明确参考号来明确标识； the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) 待诊断、治疗和/或监测的预期患者群体和医学病症以及其他考虑因素，例如患者选择标准、适应症、禁忌症、警戒； the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;

(d) 器械操作原理及其进行科学证明的操作模式（如有必要）；principles of operation of the device and its mode of action, scientifically demonstrated if necessary;

(e) 器械产品的资格理由； the rationale for the qualification of the product as a device;

(f) 器械的风险等级和按照附录 VIII 应用的分类规则的理由； the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;

(g) 任何新颖特征的说明； an explanation of any novel features;

(h) 器械附件、其他器械和非器械的其他与之配合使用产品的说明； a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;

(i) 拟市售的各种器械配置/变异型的说明或完整列表； a description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

(j) 关键功能元件的一般说明，例如其部件/组件（包括软件，如适用），其形成、组成、功能以及相关的定性和定量组成。在适当情况下，应包括带标记的图形表示（例如图表、照片和图纸），清楚指示关键部件/组件，包括充分说明理解图纸和图表； a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(k) 结合到关键功能元件中的（原）材料说明以及与人体直接或间接接触的材料说明，例如在体液的体外循环期间； a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(l) 器械技术规范（特征、尺寸和性能属性）以及通常出现在使用者可用产品规范中（例如在小册子、目录和类似出版物）的任何变量 /配置和附录。 technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.

1.2. 对前一代和类似器械的引用 Reference to previous and similar generations of the device

(a) 制造商生产的前一代器械的概述，如有； an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;

(b) 在欧盟或国际市场上发现的类似器械的概述， 如有。an overview of identified similar devices available on the Union or international markets, where such devices exist.

2. 制造商提供的信息 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

一整套 A complete set of:

- 器械及其包装（在特定管理条件下的单机包装、销售包装、运输包装）上的标签（使用器械预期销售所在成员国可接受的语言） ；the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and

- 使用说明（使用器械预期销售所在成员国可接受的语言） ；the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.

3. 设计与制造信息 DESIGN AND MANUFACTURING INFORMATION

(a) 用于理解器械设计阶段的信息； information to allow the design stages applied to the device to be understood;

(b) 完整信息和规范，包括制造过程及其验证、其佐药、连续监测和最终产品测试。应在技术文件中加入完整数据； complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

(c) 确定进行设计和制造活动的所有场地， 包括供应商和分包商。 identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

4. 通用安全与性能要求 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

文件应包含其符合附录 I 提供的通用安全与性能要求的证明信息，这些均适用于器械并考虑到其预期目的，并包括符合那些要求而采用这些解决方案的理由、 确认和验证。 该合格证明应包括： The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

(a) 适用于器械的通用安全与性能要求和其他不适用的理由； the general safety and performance

requirements that apply to the device and an explanation as to why others do not apply;

(b) 证明其符合通用安全与性能要求的方法； the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

(c) 协调标准、 CS 或采用的其他解决方案； the harmonised standards, CS or other solutions applied; and

(d) 受控文件的准确识别。该文件提供其符合各个协调标准、 CS 的证据或其他证明其符合通用安全与性能要求的方法。本点所述信息应包含在完整的技术文件中此类证据的位置的前后参照和综述技术文件（如适用）。 the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

5. 风险利益分析和风险管理 **BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT**

文件应包含以下信息： The documentation shall contain information on:

(a) 在附录 I 的第 1 和 8 节中所述的风险利益分析， the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) 所采用的解决方案和在附录 I 的第 3 节中所述的风险管理结果。 the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

6. 产品验证与确认 PRODUCT VERIFICATION AND VALIDATION

文件应包含所进行的所有验证与确认测试和 /或研究的结果和关键分析， 以证明器械符合本法规的要求，特别是证明其符合适用的通用安全与性能要求。 The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1. 临床前和临床数据 Pre-clinical and clinical data

(a) 试验结果，如工程、实验室、模拟使用和动物试验，和适用于器械的公开文献评估，并考虑其预期目的或与器械临床前安全性及其与规范一致性基本相似的器械； results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

(b) 关于测试设计、完整测试或研究协议、数据分析方法的详细信息，数据摘要和测试结论除外，尤其与以下相关内容： detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

- 器械生物相容性， 包括与患者或使用者直接或间接接触的所有材料识别； the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
- 物理、化学和微生物表征； physical, chemical and microbiological characterisation;
- 电气安全和电磁兼容性； electrical safety and electromagnetic compatibility;
- 软件验证和确认（说明软件设计和开发过程以及在成品器械中所用的软件验证证明） 。此信息通常包括在最终发布前在内部以及在模拟或实际使用者环境中执行的所有确认、验证和测试的总结结

果。其还应涉及所有不同的硬件配置，并在适用情况下， 由制造商提供信息中所确定的操作系统）；
software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

- 稳定性，包括产品有效期； stability, including shelf life; and
- 性能和安全性。 performance and safety.

在适用情况下， 应证明符合欧洲议会和理事会第 2004/10/EC 指令（[1]）的规定。 Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council (1) shall be demonstrated

若未进行新测试，文件应包括该决策的基本原理，例如，当这些性能纳入已合法投放市场或投入使用的器械的先前版本中时，需对相同材料进行生物相容性测试； Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;

(c) 根据第 61(12)条和附录 XIV 第 A 部分的临床评价报告及其更新版本以及临床评价计划； the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV;

(d) 根据附录 XIV 第 B 部分的 PMCF 计划和 PMCF 评估报告或为何 PMCF 不适用的任何合理性。 the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable.

6.2. 在特定情况下要求的附加信息 Additional information required in specific cases

(a) 若器械包含第 2001/83/EC 号指令第 1 条第 2 点规定含义内的药品物质（若单独使用） ，且作为组成部分，其中包括第 1(8)条第一子段所述的人体血液或血浆来源药品，则应附有表明这一事实的说明。在此种情况下，本文件应确定该种物质来源，并包含测试数据以评估其安全性、质量和可用性，同时需考虑器械预期目的。 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

(b) 若根据第 1(6)条(f)和(g)点，利用本法规所涵盖的人体或动物来源的组织或细胞或其衍生物制造器械，或作为不可或缺部分，若器械包含人源组织或细胞或其衍生物，其具有辅助器械的功能并根据第 1（10）条第一项涵盖在本法规中，则应附有表明这一事实的说明。在此种情况下，本文件应确定所有使用的人或动物源材料，并分别提供有关符合附录 I 第 13.1 节或第 13.2 节的详细信息。 Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.

(c) 在由旨在引入人体并由人体吸收或局部扩散至人体中的物质或物质组合构成器械的情况下，包括测试设计、完全测试或研究方案、数据分析方法的详细信息（数据摘要和测试结论除外），有关研究包括： In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

- 吸收、分布、代谢和排泄； absorption, distribution, metabolism and excretion;
- 考虑到目标人群及其相关医疗条件，该器械或人体内的物质或代谢产物与其他器械、药品或其他物质的可能相互作用； possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;
- 局部耐受性； local tolerance; and
- 毒性，包括单剂量毒性、重复剂量毒性、遗传毒性、致癌性和生殖发育毒性（根据器械总体暴露程度和性质选择）。toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

（[1]） 2004 年 2 月 11 日欧洲议会和理事会关于统一有关适用良好实验室规范原则的法律、法规和行政规定以及化学物质试验应用验证的第 2004/10/EC 号指令（ OJ L 50, 20.2.2004, p. 44）

在无此类研究的情况下，应提供理由。 In the absence of such studies, a justification shall be provided.

(d) 对于附录 I 第 10.4.1 节所述含有 CMR 或内分泌物质的器械，应按照该附录第 10.4.2 节进行论证。 In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex.

(e) 对于在无菌或定义的微生物条件下投放于市场的器械，其相关制造步骤的环境条件的说明。对于在无菌条件下投放于市场的器械，所用方法的说明，包括有关包装、消毒和无菌维护的确认报告。确认报告应所述生物负荷测试、热原测试和消毒剂残留物测试（如适用）。In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

(f) 对于投放于市场的具有测定功能的器械，为确保规范准确性而用的方法的说明。 In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

(g) 若器械需连接至其他器械以便按预期操作，则该组合/配置的说明须包括证明其在连接至任何符合制造商规定特性的此种器械时，该器械符合通用安全与性能要求。 If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

附录 **III** **ANNEX III**

关于上市后监管的技术文件

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

应以清楚的、有组织的、易搜索的和明确的方式呈现按照第 83 至 86 节由制造商草拟的关于上市后监管的技术文件，特别是应该包括本附录所述要素： The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

1.1. 根据第 84 条的上市后监管计划。 The post-market surveillance plan drawn up in accordance with Article 84.

在上市后监管计划中，制造商应证明其履行了第 83 条中所述的义务。 The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 83.

(a) 上市后监管计划应所述可用信息的收集与利用，尤其是： The post-market surveillance plan shall address the collection and utilization of available information, in particular:

- 有关严重事件的信息，包括 PSUR 的信息和现场安全纠正措施； information concerning serious incidents, including information from PSURs, and field safety corrective actions;
- 所述非严重事件的记录和有关任何不良副作用的数据； , records referring to non-serious incidents and data on any undesirable side-effects;
- 趋势报告的信息； information from trend reporting;
- 相关专家或技术文献、数据库和 /或登记表； relevant specialist or technical literature, databases and/or registers;
- 信息，包括使用者、经销商和进口商提供的反馈和投诉；和 information, including feedbacks and complaints, provided by users, distributors and importers; and
- 关于类似医疗器械的公用信息。 publicly available information about similar medical devices.

(b) 上市后监管计划至少应包括： The post-market surveillance plan shall cover at least:

- 收集（ a）点中所述的所有信息的前瞻性与系统化流程。该流程应正确地说明器械的性能，并将该器械与投放于市场的类似产品进行比较； a proactive and systematic process to collect any information referred to in point (a). The process shall allow a correct characterisation of the performance of the devices and shall also allow a comparison to be made between the device and similar products available on the market;
- 有效且适当的方法与流程，用于评估所收集的数据； effective and appropriate methods and processes to assess the collected data;
- 合适的指标和阈值，用于风险利益分析和风险管理连续的重新评估，如附录 I 第 3 节所所述的； suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in Section 3 of Annex I;
- 有效且适当的方法和工具，用于研究现场收集的投诉并分析市场相关经验； effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
- 方法和方案，用于管理那些受制于趋势报告的事件，如第 88 条所提供的，包括在统计上事件发生

频率或严重程度以及观察期的显著增加； methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

- 方法和方案，用于与主管机构、认证机构、经济运营商和使用者有效沟通； methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users;
- 参考履行第 83、84 和 86 条规定的制造商义务步骤； reference to procedures to fulfil the manufacturers obligations laid down in Articles 83, 84 and 86;
- 系统化程序，用于确定并采取适当的措施，包括纠正措施； systematic procedures to identify and initiate appropriate measures including corrective actions;
- 有效的工具，用于跟踪并确定哪些纠正措施所必需的器械； effective tools to trace and identify devices for which corrective actions might be necessary; and
- 根据附录 XIV 第 B 部分的 PMCF 计划，或为何不适用 PMCF 的理由。 a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.

1.2 如第 86 条所述的 PSUR 和第 85 条的上市后监管报告。 The PSUR referred to in Article 86 and the post-market surveillance report referred to in Article 85.

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附录 IV ANNEX IV

欧盟符合性声明 EU DECLARATION OF CONFORMITY

欧盟符合性声明应包含以下所有信息： The EU declaration of conformity shall contain all of the following information:

1. 在第 31 条中所述的制造商的名称、注册商品名或注册商标和 SRN（如签发）及其授权代表（如适用）和注册营业地点的联系地址； Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;

2. 由制造商自行负责发出的欧盟符合性声明； A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;

3. 附录 VI 第 C 部分所所述的基本的 UDI - DI ；The Basic UDI-DI as referred to in Part C of Annex VI;

4. 产品和商品名、产品代码、目录编号或其他明确的参考号，包括欧盟符合性声明所涵盖的器械的识别和可追溯性，如适当照片以及其预期目的。除产品或商品名称外，如第 3 点所述的基本 UDI - DI 提供允许识别和可追溯性信息； Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;

5. 按照附录 VIII 提出的规则，器械风险等级； Risk class of the device in accordance with the rules set out in Annex VIII;

6. 当前声明所涵盖的器械符合本法规和其他相关的欧盟立法以及联盟立法 （规定发布欧盟符合性声明的要求） （如适用）；A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;

7. 关于合格声明所用的任何 CS 的参考文献； References to any CS used and in relation to which conformity is declared;

8. 如适用，公告机构的名称和标识号， 所执行的符合性评估程序的说明和所签发的证书的标识； Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;

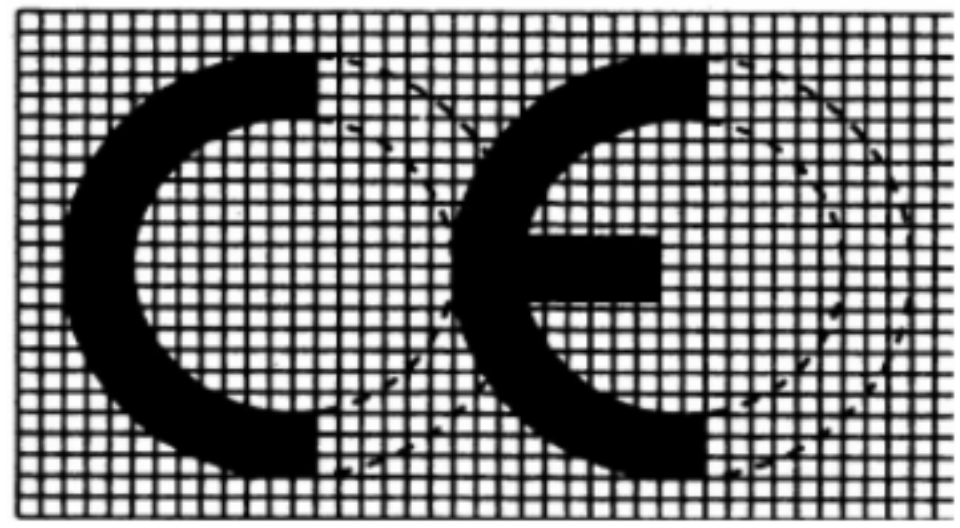
9. 如适用，额外的信息； Where applicable, additional information;

10. 签字人的声明，地址和日期、签字人姓名和职务、以及代签人签名。 Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

附录 V ANNEX V

CE 符合性标志 CE MARKING OF CONFORMITY

1. “ CE ”标识必须包含前缀“ CE ”，并采用下面形式： The CE marking shall consist of the initials ‘ CE’ ta following form:



2. 若缩小或放大 CE 标识，应遵守上述渐变图的比例。 If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.

3. 在垂直方向上， CE 标识的各个部分应具有基本相同的尺寸， 且不小于 5 mm。此最小尺寸不针对小型器械。 The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.

附录 **VI** **ANNEX VI**

根据第 **29(4)**和 **31** 条提交的注册器械和经济运营商信息，根据第 **28** 和 **29** 条提供给 **UDI** 数据库的核心数据元素与 **UDI-DI** ，和 **UDI** 系统

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

第 **A** 部分 **PART A**

根据第 **29(4)**和 **31** 条提交的注册器械和经济运营商信息

INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31

制造商、授权代表（如适用） 、进口商（如适用）应提交第 1 节中所述的信息，还应确保第 2 节中所述的有关其器械的信息是完整的和正确的，并由相关方更新。 Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in Section 1 and shall ensure that the information on their devices referred to in Section 2 is complete, correct and updated by the relevant party

1. 与经济运营商有关的信息 Information relating to the economic operator

1.1. 经济运营商的类型（制造商、授权代表或进口商） ；type of economic operator(manufacturer, authorised representative, or importer),

1.2. 经济运营商的名称、地址和联系方式； name, address and contact details of the economic operator,

1.3. 若信息由 1.1 节中的其他角色代为提交，还应提供提交人的姓名、地址和联系方式； where submission of information is carried out by another person on behalf of any of the economic operators mentioned under Section 1.1, the name, address and contact details of that person,

1.4. 第 15 条中所述的法规符合性负责人的姓名、 地址和联系方式； name address and contact details of the person or persons responsible for regulatory compliance referred to in Article 15.

2. 与器械有关的信息 Information relating to the device

2.1. 基本 UDI-DI Basic UDI-DI

2.2. 由公告机构签发证书的类型、编号和到期日以及该公告机构的名称或标识号，以及由公告机构和在公告机构和证书的电子系统中输入显示证书的信息链接。 type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate and was entered by the notified body in the electronic system on notified bodies and certificates,

2.3. 器械应投放或已经投放的市场所在的欧盟成员国； Member State in which the device is to or has been placed on the market in the Union,

2.4. 对于 IIa、IIb 或 III 类器械：该器械在该成员国中可用, in the case of class IIa, class IIb or class III devices: Member States where the device is or is to be made available

2.5. 器械的风险等级； risk class of the device,

2.6. 回收一次性使用器械（是 /否）, reprocessed single-use device (y/n),

2.7. 存在某一单独使用时可认为是一种药品的物质以及该物质的名称, presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance,

2.8. 存在某一单独使用时可认为是一种人体血液或血浆来源药品的物质以及该物质的名称, presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance,

2.9. 存在人体源组织或细胞或其衍生物（是 /否）, presence of tissues or cells of human origin, or their derivatives (y/n),

2.10. 存在第 722/2012 号法规所述动物源组织或细胞或其衍生物 （是 /否）, presence of tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 (y/n),

2.11. 如适用，与器械相关的临床研究唯一识别号（或在电子系统中与临床研究有关的临床研究登记链接） ， where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,

2.12. 对于附录 XVI 所列器械，规定器械预期目的是否为医疗用途, in the case of devices listed in Annex XVI, specification as to whether the intended purpose of the device is other than a medical purpose,

2.13. 若器械由第 10(15)条中所述的另一个法人或自然人设计和制造，法人或自然人的名称、地址和联系方式； in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that legal or natural person,

2.14. 对于 III 类器械或可植入器械，安全和临床性能总结, in the case of class III or implantable devices, the summary of safety and clinical performance,

2.15. 器械的状态（在市场上、不再在市场上、召回、现场安全纠正措施启用） 。 status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

第 **B** 部分 PART B

根据第 **28** 和 **29** 条提供给 **UDI** 数据库的核心数据元素与 **UDI-DI**

CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29

制造商应向 UDI 数据库提供 UDI-DI 以及与制造商和器械相关的以下信息： The manufacturer shall provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device:

1. 各程序包配置的数量, quantity per package configuration,

2. 第 29 条所述的基本 UDI - DI 和额外 UDI - D， the Basic UDI-DI as referred to in Article 29 and any additional UDI-DIs,

3. 控制器械生产的方式 （到期日期或生产日期、 批号或批数、 序列号）；the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number),

4. 如适用，“ UDI-DI ”使用单位（未给器械标签 UDI ‘使用单位 时，应规定 DI 使用单位 ；以便将器械的使用与患者关联起来） ， if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a ‘ unit of use ’ DI shall be assigned so as to associate the use of a device with a patient),

5. 制造商的名称和地址（如标签所示） ， name and address of the manufacturer (as indicated on the label),

6. 按照 31(2)条签发的 SRN the SRN issued in accordance with Article 31(2),

7. 如适用，授权代表的名称和地址 （如标签所示） if applicable, name and address of the authorised representative (as indicated on the label),

8. 第 26 条规定的医疗器械命名法规 the medical device nomenclature code as provided for in Article 26,

9. 器械的风险等级； risk class of the device,

10. 如适用，商品名或商标名称； if applicable, name or trade name,

11. 如适用，器械的型号、参考号或目录号； if applicable, device model, reference, or catalogue number,

12. 如适用， 临床尺寸 （包括体积、 长度、规范、 直径），if applicable, clinical size (including volume, length, gauge, diameter),

13. 额外的产品说明（可选） ；additional product description (optional),

14. 如适用，存储和 /或处理条件（如标签或使用说明所示） ；if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),

15. 如适用，器械的额外商品名； if applicable, additional trade names of the device,

16. 标记为一次性使用器械（是 /否）；labelled as a single-use device (y/n),

17. 如适用，重复使用最大次数； if applicable, the maximum number of reuses,

18. 标记为无菌的器械（是 /否）；device labelled sterile (y/n),

19. 使用前需消毒（是 /否）；need for sterilisation before use (y/n),

20. 标记为含胶乳（是 /否）， containing latex (y/n),

21. 如适用，按照附录 I 第 10.4.5 节标记的信息。 where applicable, information labelled in accordance with Section 10.4.5 of Annex I,

22. 额外信息的 URL ，如电子使用说明（可选） ；URL for additional information, such as electronic instructions for use (optional),

23. 重要警告或禁忌（如适用） 。 if applicable, critical warnings or contra-indications,

24. 器械状态（市售、不再市售、召回、现场安全纠正措施启用） status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

第 **C** 部分 PART C

UDI 系统 THE UDI SYSTEM

1. 定义 Definitions

自动标识和数据捕获（ “ AIDC ”） Automatic identification and data capture (‘ AIDC’)

AIDC 是一种自动捕获数据的技术。 AIDC 技术包括条形码、 智能卡、生物识别和 RFID。AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

基本的 UDI –DI Basic UDI-DI

基本的 UDI - DI 是器械模型的主要标识符。 基本的 UDI - DI 是在器械使用单位的层面上分配的 DI。基本的 UDI - DI 是在 UDI 数据库中记录的主键，也应在相关的证书和合格声明中引用。 The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

使用单位 DI Unit of Use DI

当 UDI 未在个别器械使用单位级别上标记时，使用单元 DI 用于在某些情况下将器械与对患者 /在患者上使用的数据相关联，例如在相同器械的若干单元的情况下包装在一起。 The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

可配置的器械 Configurable device

可配置的器械是一种由数个组件组成的器械。在多种配置中，这些组件可能由制造商组装。那些独立的组件可能本身就是器械。 A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

可配置器械包括计算机断层扫描（ CT）系统、超声系统、麻醉系统、生理监测系统、放射信息系统（ RIS）。Configurable devices include computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological Monitoring systems, radiology information systems (RIS).

配置 Configuration

配置是由制造商指定的设备项的组合，这些设备项一起运作，相当于一台器械，以达到预期目的。可修改、调整或定制设备项的组合， 以满足特殊需求。 Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customized to meet specific needs.

除其他以外，配置还包括： Configurations include inter alia:

- 台架、 管、工作台、 控制台和其他可配置 /组合以在计算机断层扫描中实现预期功能的设备项目。 gantries, tubes, tables, consoles and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.
- 提供组合呼吸机、呼吸管路、喷雾器用于麻醉的预期功能。 ventilators, breathing circuits, vaporizers combined to deliver an intended function in anaesthesia.

UDI –DI UDI-DI

UDI - DI 是专用于器械模型的唯一数字或字母数字码，也被用作 UDI 数据库中所保存的信息的“存取键”。The UDI- DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the ‘key’ to information stored in a UDI database.

人可读解释（“HRI”） Human Readable Interpretation (‘HRI’)

HRI 是 UDI 载体中编码的数据字符的易读解释。 HRI is a legible interpretation of the data characters encoded in the UDI carrier.

包装等级 Packaging levels

包装水平是指包含限定数量器械的各种水平器械包装，例如，各纸箱或箱子。 Packaging levels means the various levels of device packaging that contain a defined quantity of devices, such as a carton or case.

UDI - PI

UDI - PI 是一种数字或字母数字码，用于识别器械生产单位。 The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

不同类型的 UDI - PI 包括序列号、批号、软件标识和 /或制造和 /或到期日或上述两种日期。 The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

无线射频标识 RFID Radio Frequency Identification RFID

RFID 是一种以标识为目的通过无线电波交换阅读器和电子追踪器之间的数据来进行通信的技术。 RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.

海运集装箱 Shipping containers

海运集装箱是一种利用物流系统专用流程控制溯源的集装箱。 A shipping container is a container in relation to which traceability is controlled by a process specific to logistics systems.

唯一器械标识（“ 'UDI ”） Unique Device Identifier (‘ UDI ’）

UDI 是通过全球接受的器械标识和编码标准来创建的一系列数字或字母数字字符, 。在市场上， 允许明确标识特定器械。 UDI 由 UDI - DI 和 UDI - PI 组成。 The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

“ 唯一 ”这个词并不意味着各生产单位的序列化。 The word ‘ Unique ’ does not imply serialisation of individual production units.

UDI 载体 UDI carrier

UDI 载体是通过使用 AIDC 及其 HRI（如适用）传达 UDI 的工具。The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, its HRI.

除此以外， 载体还包括 ID / 线性条形码、 2D /矩阵条形码、 RFID 。UDI carriers include, inter alia, ID/linear bar code, 2D/Matrix bar code, RFID

2. 一般要求 General requirements

2.1. 标记 UDI 是额外要求 - 不可替换本法规附录 I 所述的任何其他标记或标签要求。 The affixing of the UDI is an additional requirement — it does not replace any other marking or labelling requirements laid down in Annex I to this Regulation.

2.2. 制造商应指定并维护其器械的唯一 UDI 。 The manufacturer shall assign and maintain unique UDIs for its devices.

2.3. 只有制造商可在其器械或包装上设置 UDI 。 Only the manufacturer may place the UDI on the device or its packaging.

2.4. 根据第 27(2)条, 只能使用由委员会所指定颁发实体提供的编码标准。 Only coding standards provided by issuing entities designated by the Commission pursuant to Article 27(2) may be used.

3. **UDI** （唯一器械标识）

3.1. UDI 应位于器械本身或其包装上。更高级别的包装应有其自己的 UDI 。 A UDI shall be assigned to the device itself or its packaging. Higher levels of packaging shall have their own UDI.

3.2. 运输容器应豁免第 3.1 节要求。例如，物流设备上无需有 UDI ；当医疗服务机构订购多台使用 UDI 或单个器械型号的器械，而且制造商将这些器械放置在一个容器内运输或用以保护单独包装的器械时，不得要求运输容器（物流设备）上有 UDI 。Shipping containers shall be exempted from the requirement in Section 3.1. By way of example, a UDI shall not be required on a logistics unit; where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) shall not be subject to UDI requirements.

3.3. UDI 应包含两部分： UDI - DI 和 UDI - PI 。The UDI shall contain two parts: a UDI-DI and a UDI-PI.

3.4. UDI - DI 在各级别的器械包装上均是唯一的。 The UDI-DI shall be unique at each level of device packaging.

3.5. 若标签上出现批号、 序列号、软件标识或过期日期，则其将是 UDI - PI 一部分。若标签上同时还标有生产日期，则 UDI - PI 中无需包含生产日期。若在标签上只有生产日期，则应将其用作 UDI - PI 。 If a lot number, serial number, software identification or expiry date appears on the label, it shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.

3.6. 被视为器械且可在市场上购买的各组件应有其单独 UDI，除非此类组件是以单独 UDI 销售的可配置器械的一部分。 Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

3.7. 应分配第 22 条所述的系统和程序包并承担自身的 UDI 。Systems and procedure packs as referred to in Article 22 shall be assigned and bear their own UDI.

3.8. 制造商应根据以下编码标准为器械指定 UDI 。The manufacturer shall assign the UDI to a device following the relevant coding standard.

3.9. 在有可能导致器械的错误识别和 /或其追溯性不明确时，尤其是以下任何 UDI 数据库元素发生的变化需要新的 UDI - DI 时，将需要提供新的 UDI - DI 。A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability; in particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(a) 名称或商标名称， name or trade name,

(b) 器械类型或型号， device version or model,

(c) 标记为一次性使用 labelled as single use,

(d) 无菌包装， packaged sterile,

(e) 使用前需消毒， need for sterilization before use,

(f) 包装中所提供器械的数量， quantity of devices provided in a package,

(g) 重要警告或禁忌症：例如含胶乳或 DEHP。

3.10. .重新包装和 /或重新安装器械的制造商，使用自身的标签，且应保留原始设备制造商（ OEM ）UDI 的记录。Manufacturers that repackage and/or relabel devices, with their own label shall retain a record of the original device manufacturer's UDI.

4. UDI 载体 UDI carrier

4.1. 应将 UDI 载体（UID 的 AIDC 和 HRI 标示）放置在标签上或器械本体上以及所有更高级别的器械包装上。 更高级别的包装不包括运输容器。 The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

4.2. 若使用包装的器械上有明显的空间限制，UDI 载体可放置在下一个更高级别的包装上。In the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

4.3. 对于单独包装和贴标签的 I 和 IIa 类一次性使用器械，不得要求 UDI 载体出现在包装上，但应出现在更高级别的包装上，如包含几个单独包装器械的纸箱。但当医疗保健提供者不能获得（家庭保健设置）更高级别的器械包装，UDI 应放置在个别器械的包装上。For single-use devices of classes I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging, e.g. a carton containing several individually packaged devices. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging of the individual device.

4.4. 对于专门用于零售销售点（POS）的器械，AIDC 中的 UDI-PI 不需要出现在销售点包装上。For devices exclusively intended for retail point of sale the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

4.5. 当除 UDI 载体外的 AIDC 载体是产品标签的一部分时，UDI 载体应易于识别。When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

4.6. 若使用线性条形码，则 UDI - DI 和 UDI - PI 可在两个或更多的条形码中进行级联或非级联。线性条形码的所有部分和元素应是可区分和可识别的。If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.

4.7. 若存在限制在标签上使用 AIDC 和 HRI 的显著约束，则标签上只需要出现 AIDC 格式。对于预期在医疗服务机构以外使用的器械（例如家庭护理器械），应在标签上使用 HRI 格式，即使会导致无空间留给 AIDC 。If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC.

4.8. HRI 格式应遵循 UDI 代码颁发实体的规则。The HRI format shall follow the rules of the UDI code-issuing entity.

4.9. 若制造商使用 RFID 技术，则应在标签上提供符合指定颁发实体所规定标准的线性或二维条形码。If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

4.10. 可重复使用的器械上应带有 UDI 载体。需要在患者使用之间进行消毒、灭菌或重新清理的可重复使用器械的 UDI 载体在每次进行处理以使器械准备好在器械的整个预期使用寿命内进行后续使用之后应是永久的和可读的。本节的规定不适用于满足以下任一条件的任何器械：Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances:

(a) 任何类型的直接标记将对器械的安全或性能造成干扰；any type of direct marking would interfere with the safety or performance of the device;

(b) 该器械不能直接标记，因为其在技术上并非切实可行。the device cannot be directly marked because it is not technologically feasible.

4.11. UDI 载体在器械正常使用和预期使用寿命内应是可读的。The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

4.12. 若 UDI 载体容易通过器械的包装或在 AIDC 可扫描的情况下读取，则无需将 UDI 载体放置在包装上。If the UDI carrier is readily readable or, in the case of AIDC, scannable, through the device's packaging, the placing of the UDI

carrier on the packaging shall not be required.

4.13. 若由多个部件组成且在首次使用前必须完成装配, 单独成品器械, 则其将 UDI 载体仅放置在各器械的一个部分上。 In the case of single finished devices made up of multiple parts that must be assembled before their first use, it shall be sufficient to place the UDI carrier on only one part of each device.

4.14. UDI 载体的位置应合理, 以使在正常操作或储存期间可进行 AIDC 。The UDI carrier shall be placed in a manner such that the AIDC can be accessed during normal operation or storage.

4.15. 包括“ UDI - DI ”和“ UDI - PI ”的条形码载体还可包含器械操作的基本数据或其他数据。 Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

5. UDI 数据库的一般原则 General principles of the UDI database

5.1. UDI 数据库应支持本附录第 B 部分所述的所有 UDI 数据库核心数据元素的使用。 The UDI database shall support the use of all core UDI database data elements referred to in Part B of this Annex.

5.2. 制造商应负责首次提交和更新 UDI 数据库中的识别信息和其他器械数据元素。 Manufacturers shall be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

5.3. 应运用正确的方法和程序对提供的数据进行验证。 Appropriate methods/procedures for validation of the data provided shall be implemented.

5.4. 制造商应定期对与其投放到市场上的器械相关的所有数据进行核实, 除非这些器械从市场上撤出。 Manufacturers shall periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

5.5. UDI 数据库中存在器械 UDI –DI 不得假设该器械符合本法规的规定。 The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with this Regulation.

5.6. 数据库应允许器械不同包装级别的链接。 The database shall allow for the linking of all the packaging levels of the device.

5.7. 新的 UDI - DI 的数据应在器械投放市场时可用。 The data for new UDI-DIs shall be available at the time the device is placed on the market.

5.8. 当对不需要新 UDI - DI 的元素进行更改时, 制造商应在 30 天内更新相关的 UDI 数据库记录。 Manufacturers shall update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

5.9. 在可能的情况下, UDI 数据库应使用国际公认的数据提交和更新标准。 Internationally-accepted standards for data submission and updates shall, wherever possible, be used by the UDI database.

5.10. UDI 数据库的使用者界面应适用于欧盟的所有官方语言。但为减少翻译, 应尽可能减少自由文本字段的使用。 The user interface of the UDI database shall be available in all official languages of the Union. The use of free-text fields shall, however, be minimized in order to reduce translations.

5.11. 与市场上不再使用的器械相关的数据应保存在 UDI 数据库中。 Data relating to devices that are no longer available on the market shall be retained in the UDI database.

6. 特定器械类型的规则 Rules for specific device types

6.1. 可植入器械 Implantable devices:

6.1.1. 可植入器械应在其最低包装水平 (“ 单位包装 ”) 下用 UDI（UDI-DI + UDI-PI ）或 AIDC 识别或标记； Implantable devices shall, at their lowest level of packaging (‘ unit packs ’), be identified, or marked using AIDC, with a UDI

(UDI-DI + UDI-PI);

6.1.2. UDI-PI 应至少具有以下特征： The UDI-PI shall have at least the following characteristics:

(a) 有源可植入器械的序列号, the serial number for active implantable devices,

(b) 其他可植入器械的序列号或批号； the serial number or lot number for other implantable devices.

6.1.3. 可植入器械的 UDI 在植入前应是可识别的。 The UDI of the implantable device shall be identifiable prior to implantation.

6.2. 可重复使用的器械在使用期间需要清洁、消毒、灭菌或重新清理 Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses

6.2.1. 此类器械的 UDI 应置于器械上，而且在各操作程序后都是可读的，以便于器械的下次使用； The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use.

6.2.2. 制造商应对 UDI-PI 的特性（例如批号或序列号） 进行定义。 The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

6.3. 第 22 条所述的系统和手术包 Systems and procedure packs as referred to in Article 22

6.3.1. 第 22 条所述的自然人和法人应负责使用包括 UDI - DI 和 UDI - PI 的 UDI 来识别系统或手术包； The natural or legal person referred to in Article 22 shall be responsible for identifying the system or procedure pack with a UDI including both UDI-DI and UDI-PI.

6.3.2. 系统或手术包的器械内件应将 UDI 载体置于其包装上或器械本身上。 Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself.

6.3.3. Exemptions

豁免 Exemptions：

(a) 对于系统或手术包内的单独一次性使用的一次性使用器械，其用途一般为其拟使用的人所知，并且不适用于在系统或手术包范围以外的人员使用，则不需要在其上设置 UDI 载体。 individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier;

(b) 豁免在相关级别包装上设置 UDI 载体的器械，在加入系统或手术包内时，其上无需设置 UDI 载体。 devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.

6.3.4. UDI 载体设置在系统或手术包上： Placement of the UDI carrier on systems or procedure packs

(a) 系统或手术包的 UDI 载体通常应贴在包装外面； The system or procedure pack UDI carrier shall as a general rule be affixed to the outside of the packaging.

(b) 无论是放置在系统或手术包包装的外部, 还是放在透明包装内, UDI 载体都应是可读的, 或可供 AIDC 扫描。 The UDI carrier shall be readable, or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging.

6.4. 可配置器械 Configurable devices:

6.4.1. UDI 应全部分配给可配置器械, 并定名为可配置器械 UDI 。 A UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI.

6.4.2. 可配置器械 UDI - DI 应分配给配置组, 而不是组内的各配置。 一组配置应定义为技术文件中所说明的给定器械的可能配置。 The configurable device UDI-DI shall be assigned to groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation.

6.4.3. 应将可配置器械 UDI - PI 分配给各单独的可配置器械。 A configurable device UDI-PI shall be assigned to each individual configurable device.

6.4.4. 可配置器械 UDI 的载体应放置在最不可能在系统使用期间进行更换的组件上, 并且应认定为可配置器械 UDI The carrier of the configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the configurable device UDI. 。

6.4.5. 各可视为器械并且可自行购买的组件应分配一个单独的 UDI ；Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI.

6.5. 器械软件 Device Software

6.5.1. UDI 指定标准 UDI assignment Criteria

应按软件的系统级别指定 UDI 。只有可自行购买的软件和本身就是器械的软件才应遵循该要求。 The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.

软件标识应视为制造控制机制，并显示在 UDI - PI 中。 The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.

6.5.2 每当修改改变时, 需要新的 UDI - DI ：A new UDI-DI shall be required whenever there is a modification that changes:

(a) 原始性能和疗效, the original performance;

(b) 软件安全或预期用途。 the safety or the intended use of the software;

(c) 数据解释。 interpretation of data.

此类变化可能包括新的或修改的算法、数据库结构、操作平台、架构、新的使用者界面或用于互操作性的新渠道。 Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.5.3. 次要软件修订版本应需要一个新的 UDI - PI （而不是新的 UDI - DI ）：Minor software revisions shall require a new UDI-PI and not a new UDI-DI.

次要软件修订版本通常与错误修复、可用性增强相关，而非出于安全目的、安全补丁或运行效率。 Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

次要软件修订版本应通过制造商的特定标识形式予以识别。 Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.5.4. 软件的 UDI 配置标准 UDI placement criteria for software

(a) 当软件以 CD 或 DVD 等物理介质进行交付时，各包装级别应以人类可读和完整 UDI 的 AIDC 表示。且应用于包含软件及其包装的物理介质的 UDI 应与分配给系统级软件的 UDI 相同；where the software is delivered on a physical medium, e.g. CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;

(b) UDI 应以容易读取的纯文本格式（例如，“关于”文件或包括在启动屏幕上）提供在使用者容易访问的屏幕上；the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain- text format, such as an ‘aboutor’ file, included on the start-up screen;

(c) 缺少使用者界面的软件（例如，用于图像转换的中间软件）应能够通过应用程序编程接口（API）发送 UDI；software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);

(d) 软件的电子显示器上只需要 UDI 的人类可读部分。使用 AIDC 标记的 UDI 不得用于电子显示器，如“关于”菜单、欢迎界面等；only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays, such as ‘about nu, splash screen etc.;

(e) 软件 UDI 的人类可读格式应包括颁发实体的所使用标准的应用标识符（AI），以便帮助使用者识别 UDI 并确定用来创建 UDI 的标准。the human readable format of the UDI for the software shall include the Application Identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

附录 VII ANNEX VII

公告机构需满足的要求 REQUIREMENTS TO BE MET BY NOTIFIED BODIES

1. 组织和一般要求 ORGANISATIONAL AND GENERAL REQUIREMENTS

1.1. 法人资格和组织结构 Legal status and organisational structure

1.1.1. 应根据成员国的国内法, 或根据与欧盟达成该方面协议的第三方国家的法律来建立各公告机构, 并应对其法人资格和地位进行全面记录。此类记录应包括关于所有权和对公告机构行使控制权的法人或自然人的信息。

Each notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect. Its legal personality and status shall be fully documented. Such documentation shall include information about ownership and the legal or natural persons exercising control over the notified body.

1.1.2. 若公告机构是作为较大组织一部分的法人实体, 则该组织的活动及其组织结构和管理以及与公告机构的关系应清楚地记录在案。在这种情况下, 第 1.2 节的要求适用于公告机构和其所属的组织。 If the notified body is a legal entity that is part of a larger organisation, the activities of that organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented. In such cases, the requirements of Section 1.2 are applicable to both the notified body and the organisation to which it belongs.

1.1.3. 若公告机构全部或部分拥有在成员国或第三方国家建立的法人实体, 或由另一法人实体所拥有, 则应对这些实体的活动和责任, 以及其与公告机构的法律和业务关系进行明确的定义和记录。 根据本法规进行符合性评估活动的实体人员应遵守本法规的适用要求。 If a notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented. Personnel of those entities performing conformity assessment activities under this Regulation shall be subject to the applicable requirements of this Regulation.

1.1.4. 公告机构的组织结构、 责任分配、 汇报程序和运作应能确保其对公告机构的性能所进行符合性评估活动的结果有信心。 The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that they ensure that there is confidence in the performance by the notified body and in the results of the conformity assessment activities it conducts.

1.1.5. 公告机构应清楚地记录其组织结构、 高层管理人员和其他可能影响公告机构的性能以及符合性评估活动结果的人员的职能、职责和权限。 The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance by the notified body and upon the results of its conformity assessment activities.

1.1.6. 公告机构应确定对以下各项具有最高决策权和责任的高层管理人员： The notified body shall identify the persons in top-level management that have overall authority and responsibility for each of the following:

- 为符合性评估活动提供足够的资源； the provision of adequate resources for conformity assessment activities;
- 制定公告机构运作程序和政策； the development of procedures and policies for the operation of the notified body;

- 监管公告机构的监管程序、 政策和质量管理体系； the supervision of implementation of the procedures, policies and quality management systems of the notified body;
- 监管公告机构的财务； the supervision of the notified body's finances;
- 公告机构的活动和决议，包括合同协议； the activities and decisions taken by the notified body, including contractual agreements;
- 在必要时向人员和（或）委员会授予执行既定活动的权力；和 the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities;
- 与负责公告机构的主管机构的互动，以及与其他主管机构、委员会和其他公告机构沟通的义务。 the interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.

1.2. 独立性和公正性 Independence and impartiality

1.2.1. 公告机构应为独立于进行符合性评估活动的器械制造商的第三方机构。 公告机构也应独立于对器械以及制造商的任何竞争对手有利害关系的任何其他经济运营商。这并不妨碍公告机构对竞争制造商的符合性评估活动.

The notified body shall be a third-party body that is independent of the manufacturer of the device in relation to which it performs conformity assessment activities. The notified body shall also be independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer. This does not preclude the notified body from carrying out conformity assessment activities for competing manufacturers. 。

1.2.2. 公告机构的组织和运作应保障其活动的独立性、客观性和公正性。公告机构应记录和实施一种结构和程序，以保障其公正性，并在其整个组织、人员和评估活动中促进和使用公正性原则。此类程序应可识别、研究和解决任何情况，其中可能发生利益冲突，包括在公告机构开展工作之前参与器械领域的咨询服务。研究、结果及其解决方案应记录在案。 The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. Such procedures shall provide for the identification, investigation and resolution of any case in which a conflict of interest may arise, including involvement in consultancy services in the field of devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.

1.2.3. 公告机构、其高层管理人员及负责执行符合性评估任务的人员不得 The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) 是所评估器械的设计师、制造商、供应商、安装者、购买者、所有者或维护者，也不得是此类各方的授权代表。此类限制不妨碍购买和使用公告机构运营所必需的评估器械， 以及进行符合性评估或为个人目的使用此类器械； be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(b) 参与其指定器械的设计、制造或建造、营销、安装和使用或维护，也不得代表参与这些活动的各方。 be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of

the devices for which they are designated, nor represent the parties engaged in those activities;

(c) 参与可能与其指定的符合性评估活动相关的判断或诚信发生冲突的任何活动； engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated;

(d) 提供可能对其独立性、公正性或客观性的置信度产生损害的任何服务。特别是，其不得向制造商、其授权代表、 供应商或商业竞争对手提供有关被评估器械或过程的设计、 建造、 销售或维护的咨询服务。 offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, and

(e) 与任何本身能提供（ d）点所述咨询服务的组织相联系。这并不妨碍非客户特定并涉及器械法规或相关标准相关的一般培训活动。 be linked to any organisation which itself provides consultancy services as referred to in point (d). Such restriction does not preclude general training activities that are not client specific and that relate to regulation of devices or to related standards.

1.2.4. 在公告机构开展工作之前参与医疗器械领域的咨询服务应在雇佣时充分记录在案， 并且应根据本附录对潜在的利益冲突进行监控和解决。 在公告机构开展工作之前， 不得为特定客户的前雇员提供器械领域的咨询服务的人员指派于该特定客户或属于同一组的公司的符合性评估活动，限期三年。 Involvement in consultancy services in the field of devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interest shall be monitored and resolved in accordance with this Annex. Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client prior to taking up employment with a notified body, shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of three years.

1.2.5. 应保证公告机构、 其高层管理人员和评估人员的公正性。 公告机构和参与评估活动分包商的高层管理人员和评估人员的薪酬水平不取决于评估结果。公告机构应公开其高层管理人员的利益申报。 The impartiality of notified bodies, of their top-level management and of the assessment personnel shall be guaranteed. The level of the remuneration of the top-level management and assessment personnel of a notified body and subcontractors, involved in assessment activities shall not depend on the results of the assessments. Notified bodies shall make publicly available the declarations of interest of their top-level management.

1.2.6. 若公告机构由公共实体或机构所有， 则应确保和证明独立性和不存在任何利益冲突， 一方面是负责公告机构和/或主管机构的机构，而另一方面是公告机构。 If a notified body is owned by a public entity or institution, independence and absence of any conflict of interest shall be ensured and documented between, on the one hand, the authority responsible for notified bodies and/or the competent authority and, on the other hand, the notified body.

1.2.7. 公告机构应确保并记录其子公司、分包商或任何相关机构的活动，包括其所有者的活动，而且不影响其符合性评估活动的独立性、公正性或客观性。 The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, including the activities of its owners do not affect its independence, impartiality or the objectivity of its conformity assessment activities.

1.2.8. 考虑到第 2003/361/EC 号建议中关于费用部分所定义的中小型企业的利益，公告机构应根据一套统一、公平合理的条款和条件运作。 The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to fees.

1.2.9. 本节要求绝不会妨碍公告机构和进行符合性评估的制造商之间对技术信息和规章指南的交流。 The

requirements laid down in this Section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer applying for conformity assessment.

1.3. 保密性 Confidentiality

1.3.1. 公告机构应制定文件化程序，确保其人员、委员会、子公司、分包商、任何外部相关机构或人员在符合性评估活动执行期间遵守其所拥有信息的保密性，除非法律要求披露时。 The notified body shall have documented procedures in place ensuring that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information which comes into its possession during the performance of conformity assessment activities, except when disclosure is required by law.

1.3.2. 公告机构的人员应遵守有关根据本法规或任何生效的国家法律在实施其任务时的职业性秘密，有关负责公告机构的机构、负责成员国或委员会的医疗器械的主管机构除外。所有权应受到保护。为此，公告机构应制定本节要求的合适文件化程序。 The personnel of a notified body shall observe professional secrecy in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States or the Commission. Proprietary rights shall be protected. The notified body shall have documented procedures in place in respect of the requirements of this Section.

1.4. 责任 Liability

1.4.1. 公告机构应为其合适评估活动办理适当的责任保险，除非根据国家法律由相关成员国承担责任，或成员国对符合性评估直接负责。 The notified body shall take out appropriate liability insurance for its conformity assessment activities, unless liability is assumed by the Member State in question in accordance with national law or that Member State is directly responsible for the conformity assessment.

1.4.2. 责任保险的范围和总体财务价值应与公告机构活动的水平和地理范围相对应，并与公告机构所认证器械的风险状况相称。 责任保险范围应包括公告机构可能有义务取消、限制或暂停证书的情况。 The scope and overall financial value of the liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.

1.5. 财务要求 Financial requirements

公告机构应拥有在其指定范围和相关业务活动中进行符合性评估活动所需的财政资源。考虑到初始启动阶段内的具体情况， 公告机构应在初始启动阶段考虑到相关的任何具体情况下，记录并提供能证明其财政能力和长期经济可行性证据。 The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its long-term economic viability, taking into account, where relevant, any specific circumstances during an initial start-up phase.

1.6. 参与协调活动 Participation in coordination activities

1.6.1. 指定机构应参与或确保其评估人员获悉所有相关标准化活动和第 49 条所述的公告机构协调小组的活动，并向评估和决策人员通报本法规框架内的所有相关立法、指南和最佳实践文件。 The notified body shall participate in, or ensure that its assessment personnel is informed of, any relevant standardisation activities and in the activities of the notified body coordination group referred to in Article 49 and that its assessment and decision-making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.

1.6.2 公告机构应考虑到指南和最佳实践文件。 The notified body shall take into consideration guidance and best

practice documents.

2. 质量管理要求 QUALITY MANAGEMENT REQUIREMENTS

2.1. 公告机构应建立、记录、实施、维护和运行符合其符合性评估活动性质、区域和规模的质量管理体系，并能够符合和证明其与本法规要求的一致性。 The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and is capable of supporting and demonstrating the consistent fulfilment of the requirements of this Regulation.

2.2. 公告机构的质量管理体系至少应包括以下方面： The quality management system of the notified body shall address at least the following:

- 管理体系结构和文件，包括其活动的策略和目标； management system structure and documentation, including policies and objectives for its activities;
- 有关活动人员分配及其职责的策略； policies for assignment of activities and responsibilities to personnel;
- 根据高层管理人员和其他公告机构人员的任务、职责和角色用进行的评估和决策过程； assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management;
- 计划、执行、评估和在必要时修改其合格评估流程； the planning, conduct, evaluation and, if necessary, adaptation of its conformity assessment procedures;
- 文件控制； control of documents;
- 记录控制； control of records;
- 管理评审； management reviews;
- 内部审计； internal audits;
- 整改与预防措施； corrective and preventive actions;
- 投诉和上诉； complaints and appeals; and
- 持续培训。 continuous training.

若以多种语言使用文件，则公告机构应确保并控制此类文件具有相同的内容。 Where documents are used in various languages, the notified body shall ensure and control that they have the same content.

2.3. 公告机构高层的管理人员应确保整个公告机构组织（包括根据本法规参与符合性评估活动的子公司和分包商）都充分了解、 实施和维护质量管理体系。 The top-level management of the notified body shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors involved in conformity assessment activities pursuant to this Regulation.

2.4. 公告机构应要求所有人员通过签字或类似形式正式承诺其会遵守公告机构规定的章程。 该承诺应涵盖与商业和其他利益的保密性和独立性相关的方面，以及与客户现有或之前的任何关联。人员需要填写书面声明，表明其遵守保密性、独立性和公正原则。 The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. That commitment shall cover aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel shall be required to complete written statements indicating their compliance with confidentiality, independence and impartiality principles.

3. 资源要求 RESOURCE REQUIREMENTS

3.1. 总则 General

3.1.1. 公告机构应能够以最高程度的职业操守和特定领域的必要能力来执行本法规赋予其所有任务，无论此类任务是否有其自己或代表其执行，并属于其职责范围。 Notified bodies shall be capable of carrying out all the tasks falling to them under this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether those tasks are carried out by notified bodies themselves or on their behalf and under their responsibility.

特别是，公告机构其应拥有必要的人员，并拥有或能够使用指定符合性评估活动中的技术、科学和行政任务所需的所有设备、 设施和权限。 In particular, notified bodies shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which they have been designated.

此类要求在任何时候和对于各合格评估流程及其指定的每种类型器械，均假定公告机构可永久获得有相关器械和相应技术方面的知识和经验的足够行政、技术和科研人员。考虑到本法规的规定，特别是载于附录 I 的规定，此类人员应达充分数量以确保相关公告机构可进行符合性评估任务，包括对医疗功能性的评估、对临床评价和器械的性能和安全的评估。 Such requirement presupposes at all times and for each conformity assessment procedure and each type of devices in relation to which they have been designated, that the notified body has permanent availability of sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. Such personnel shall be in sufficient numbers to ensure that the notified body in question can perform the conformity assessment tasks, including the assessment of the medical functionality, clinical evaluations and the performance and safety of devices, for which it has been designated, having regard to the requirements of this Regulation, in particular, those set out in Annex I.

公告机构的累积职权必须使其可评定其指定类型的器械。 公告机构必须具有足够的内部能力来严格评估外部专家的评估。 公告机构无法分包的任务列于本附录第 4.1 节。A notified body's cumulative competences shall be such as to enable it to assess the types of devices for which it is designated. The notified body shall have sufficient internal competence to critically evaluate assessments conducted by external expertise. Tasks which a notified body is precluded from subcontracting are set out in Section 4.1.

参与公告机构对器械符合性评估活动的管理运作的人员应具备适当的知识，以建立和运行用于选择评估和验证人员、验证其能力、授权及分配其任务、组织初始和持续培训、分配职责和监管其工作人员的系统，从而确保管理和执行评估和验证找错的人员有能力完成其所需的任务。 personnel involved in the management of the operation of a notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of assessment and verification staff, for verification of their competence, for authorisation and allocation of their tasks, for organisation of their initial and ongoing training and for the assignment of their duties and the monitoring of those staff, in order to ensure that personnel who carry out and perform assessment and verification operations are competent to fulfil the tasks required of them.

公告机构应确定至少一个其高级管理层内的个体，该个体对与器械有关的符合性评估活动负全责。 The notified body shall identify at least one individual within its top-level management as having overall responsibility for all conformity assessment activities in relation to devices.

3.1.2.. 公告机构应确保参与符合性评估活动的人员通过实施经验交流系统和持续培训以及教育计划能保持其资质和专业知识。 The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.

3.1.3. 公告机构应明确记录相关人员（包括符合性评估活动中涉及的任何分包商和外部专家）职责、责任和权限范

围和限制，并相应地通知此类人员。 The notified body shall clearly document the extent and limits of duties and responsibilities and the level of authorisation of the personnel, including any subcontractors and external experts, involved in conformity assessment activities and inform those personnel accordingly.

3.2. 相关人员的资格标准 Qualification criteria in relation to personnel

3.2.1. 公告机构应建立并记录资格标准和程序，以便选择和授权参与符合性评估活动的人员（包括所需的知识、经验和其他能力）和所需培训（初始和持续培训） 。资格标准应涵盖符合性评估过程中的各种功能（如审计、产品评估 /测试、技术文件审核、决策）以及器械、技术和指定范围内所涵盖的领域（如生物相容性、消毒、人类和动物来源的组织和细胞和临床评价） 。 The Notified Body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities, including as regards knowledge, experience and other competence required, and the required initial and ongoing training. The qualification criteria shall address the various functions within the conformity assessment process, such as auditing, product evaluation or testing, technical documentation review and decision-making, as well as the devices, technologies and areas, such as biocompatibility, sterilisation, tissues and cells of human and animal origin and clinical evaluation, covered by the scope of designation.

3.2.2. 第 3.2.1 节所述的资格标准应根据第 42(3)条中由成员国使用的通知范围说明所述公告机构的指定范围，并提供范围说明细分部分中所规定资格的足够详细信息。 The qualification criteria referred to in Section 3.2.1 shall refer to the scope of a notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 42(3), providing a sufficient level of detail for the required qualification within the subdivisions of the scope description.

应至少为以下评估确定具体的资格标准： Specific qualification criteria shall be defined at least for the assessment of:

- 临床前评估， the pre-clinical evaluation,
- 临床评价， clinical evaluation
- 人类和动物来源的组织和细胞， tissues and cells of human and animal origin,
- 功能安全， functional safety,
- 软件， software,
- 包装， packaging,
- 作为药品主要部分并入的器械， devices that incorporate as an integral part a medicinal product,
- 由人体吸收或局部喷洒在人体上的物质或组合物质组成的器械；和 devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body and
- 不同类型的灭菌过程。 the different types of sterilisation processes.

3.2.3. 由公告机构雇用负责制定资格标准和授权其他人员进行具体符合性评估活动的人员，且不得是外部专家或分包商。此外，此类人员应具备以下全部方面的足够知识和经验： The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be external experts or subcontracted. They shall have proven knowledge and experience in all of the following:

- 欧盟器械法规和相关指导性文件； Union devices legislation and relevant guidance documents;
- 符合本法规规定的合格评估流程； the conformity assessment procedures provided for in this Regulation;

- 器械技术和器械的设计和制造广泛基础知识； a broad base of knowledge of device technologies and the design and manufacture of devices;
- 公告机构质量管理体系、 相关程序和所需的资格标准； the notified body's quality management system, related procedures and the required qualification criteria;
- 培训有关参与涉及器械的符合性评估活动的人员； training relevant to personnel involved in conformity assessment activities in relation to devices;
- 具备与根据本法规或公告机构内先前适用法律进行的符合性评估相关的足够经验。 adequate experience in conformity assessments under this Regulation or previously applicable law within a notified body.

3.2.4. 公告机构应拥有具有相关临床专业知识的永久性人员（此类人员尽可能由公告机构雇用。 ）此类人员应在整个公告机构评估和决策过程中整合, 以便： The notified body shall have permanent availability of personnel with relevant clinical expertise and where possible such personnel shall be employed by the notified body itself. Such personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:

- 确定需要专家投入到由制造商进行的临床评价的评定时间，以及相应确定合资格专家； identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;
- 按照本法规的相关规定、 CS、协调标准适当训练外部临床专家并确保外部临床专家均充分了解到环境和其评定和提出建议的影响； appropriately train external clinical experts in the relevant requirements of this Regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implications of their assessment and the advice they provide;
- 能够审查和在科学上质疑包含在临床评价中的临床资料，以及任何相关的临床研究，并在制造商提供的临床评价的评定中适当引导外部临床专家； be able to review and scientifically challenge the clinical data contained within the clinical evaluation, and any associated clinical investigations, and appropriately guide external clinical experts in the assessment of the clinical evaluation presented by the manufacturer;
- 能够科学评估, （如有必要）质疑提供的临床评价以及外部临床专家对制造商的临床评价的评定结果； be able to scientifically evaluate and, if necessary, challenge the clinical evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;
- 能够确定由临床专家进行的临床评价的评定可比性和一致性； be able to ascertain the comparability and consistency of the assessments of clinical evaluations conducted by clinical experts
- 能够评定制造商的临床评价和任何外部专家提供的对于临床判断的意见，并向公告机构的决策者提出建议； be able to make an assessment of the manufacturer's clinical evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker; and
- 能够制定记录和报告，以证明已执行相关的符合性评估活动。 be able to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.5. 负责对产品进行相关审核（如技术文件审查或包括临床评价、生物安全性、杀菌、软件验证等方面的类型检查）的人员（产品审查员）应具备以下经证实资格： The personnel responsible for carrying out product-related reviews (product reviewers), such as technical documentation reviews or type examination,

including aspects such as clinical evaluation, biological safety, sterilisation and software validation, shall have all of the following proven qualifications:

- 成功获得相关专业的大学或大专学位或同等学历资格，例如，医学、制药学、工程或其他相关学科；successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;
- 在医疗保健品或相关部门（如制造，审计或研究）领域拥有四年专业经验，同时应在器械的设计、制造、测试或使用或进行评定或有关涉及科学方面评定的技术方面拥有两年经验； four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;
- 拥有器械法规方面的知识，包括附录 I 规定的一般安全与性能规定 knowledge of device legislation, including the general safety and performance requirements set out in Annex I;
- 相关协调标准、 CS 和指导性文件的适当知识和经验； appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;
- 拥有风险管理及有关医疗器械标准和指导性文件方面的相应知识和经验； appropriate knowledge and experience of risk management and related device standards and guidance documents;
- 拥有临床评价方面的相应知识和经验； appropriate knowledge and experience of clinical evaluation;
- 与其正在评估的器械相关的适当知识； appropriate knowledge of the devices which they are assessing;
- 附录 IX 至 XI 中所规定合格评估流程的适当知识和经验，特别获得授权的相关方面，以及执行此类评估的足够权限； appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those assessments;
- 能够制定记录和报告， 以证明已执行相关的符合性评估活动。 the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.6. 负责对制造商的质量管理体系进行审核的人员 （现场审核员） 应具有以下证明资格： The personnel responsible for carrying out audits of the manufacturer's quality management system (site auditors) shall have all of the following proven qualifications:

- 成功获得相关专业的大学或专科学院学位或同等学历资格，例如，医学、制药学、工程或其他相关学科；successful completion of a university or a technical college degree or equivalent qualification in relevant studies, such as medicine, pharmacy, engineering or other relevant sciences;
- 在医疗保健产品或相关行业（如制造，审计或研究）领域拥有四年专业经验，同时在这些领域有两年的质量管理经验； four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research, of which two years shall be in the area of quality management;
- 拥有器械法规及协调标准、 CS 和指导性文件方面的相应知识 appropriate knowledge of devices legislation as well as related harmonised standards, CS and guidance documents;
- 拥有风险管理及有关器械标准和指导性文件方面的相应知识和经验； appropriate knowledge and experience of risk management and related device standards and guidance documents;
- 拥有质量管理体系及相关标准和指导性文件方面的相应知识； appropriate knowledge of quality

management systems and related standards and guidance documents;

- 附录 IX 至 XI 中所规定合格评估流程的适当知识和经验，特别获得授权的相关方面，以及执行此类审计的足够权限。 appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes IX to XI, in particular of the aspects of those procedures for which they are responsible, and adequate authorisation for carrying out those audits;
- 接受审计技术培训使其拥有质疑质量管理体系的能力。 training in auditing techniques enabling them to challenge quality management systems;
- 能够制定记录和报告，以证明已执行相关的符合性评估活动。 the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.

3.2.7. 负责最终审查和认证决议的人员应当是公告机构本身的雇员，而非外部专家或分包合同。作为团体，所有这些人员，应具备以下经过考验的知识和全面经验： The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted. Those personnel shall, as a group, have proven knowledge and comprehensive experience of all of the following:

- 器械法规和相关指导性文件； devices legislation and relevant guidance documents;
- 进行有关本法规的医疗器械符合性评估； the device conformity assessments relevant to this Regulation;
- 与器械符合性评估相关的资格类型、经验和专业知识； the types of qualifications, experience and expertise relevant to device conformity assessment;
- 在器械技术方面拥有广泛基础，包括符合性评估最终认证审查器械的充足经验、器械行业和器械的设计和制造方面； a broad base of knowledge of device technologies, including sufficient experience of conformity assessment of devices being reviewed for certification, the device industry and the design and manufacture of devices;
- 公告机构质量管理体系、相关程序和涉及人员所需的资格。 the notified body's quality management system, related procedures and the required qualifications for personnel involved;
- 能够制定记录和报告，以证明已执行的符合性评估活动。 the ability to draw up records and reports demonstrating that the conformity assessment activities have been appropriately carried out.

3.3. 人员资格、培训和授权的证明文件 Documentation of qualification, training and authorisation of personnel

3.3.1. 公告机构应有一个程序，以充分记录参与符合性评估活动的各名人员的资格以及是否满足第 3.2 节中所述的资格标准。在特殊情况下，如无法充分证明是否满足第 3.2 节中规定的资格标准，公告机构应向负责公告机构的主管机构证明这些人员有权进行特定的符合性评估活动。 The notified body shall have a procedure in place to fully document the qualification of each member of personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2. Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2. cannot be fully demonstrated, the notified body shall justify to the authority responsible for notified bodies the authorisation of those members of personnel to carry out specific conformity assessment activities.

3.3.2. 对于第 3.2.3 到 3.2.7 节中所述的所有人员，公告机构应建立并保持最新的： For all of its personnel referred to in Sections 3.2.3 to 3.2.7, the notified body shall establish and maintain up to date:

- 详细说明符合性评估活动方面人员的授权和责任的模块； a matrix detailing the authorisations and

responsibilities of the personnel in respect of conformity assessment activities; and

- 证明其获得授权的符合性评估活动所需的知识和经验的记录。记录文件应包含确定各评估人员合理的责任范围和各人进行的符合性评估活动的记录。 records attesting to the required knowledge and experience for the conformity assessment activity for which they are authorised. The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.

3.4. 分包商和外部专家 Subcontractors and external experts

3.4.1. 在不影响第 3.2 节的限制的情况下，公告机构可转包符合性评估活动的某些明确定义的组成部分。 Notified bodies may, without prejudice to Section 3.2, subcontract certain clearly defined component parts of a conformity assessment activity.

不允许对整个质量管理体系或产品检验相关的审核进行分包， 但这些活动的某些部分可由分包商和外部审核员以及专家代表公告机构执行。 相关公告机构能够对提供分包商和专家实现其特定任务的能力的证据负全部责任， 并保留对根据分包商评定所做出决策应负的责任， 以及对分包商和专家代表其进行的工作负有全部责任。The subcontracting of the auditing of quality management systems or of product related reviews as a whole shall not be permitted; nevertheless parts of those activities may be conducted by subcontractors and external auditors and experts working on behalf of the notified body. The notified body in question shall retain full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil their specific tasks, for making a decision based on a subcontractor's assessment and for the work conducted by subcontractors and experts on its behalf.

以下活动不得由公告机构转包： The following activities may not be subcontracted by notified bodies:

- 审查外部专家的资格和监测其性能； review of the qualifications and monitoring of the performance of external experts;
- 涉及相关分包的审计或认证组织的审计及认证活动； auditing and certification activities where the subcontracting in question is to auditing or certification organisations
- 将工作分配给外部专家进行具体的符合性评估活动； allocation of work to external experts for specific conformity assessment activities; and
- 最终审查和决策职能。 final review and decision making functions.

3.4.2. 若公告机构将某些符合性评估活动分包给某个组织或个人，则其应有一个说明允许进行分包的条件的政策，并应确保： Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:

- 分包商符合本附录的有关规定； the subcontractor meets the relevant requirements of this Annex;
- 分包商和外部专家不再将工作转包给组织或人员； subcontractors and external experts do not further subcontract work to organisations or personnel; and
- 第一和第二个缩进中所述的要求已经告知申请符合性评估的自然人或法人 the natural or legal person that applied for conformity assessment has been informed of the requirements referred to in the first and second indent.

外部人员的任何分包或咨询应有适当的文件记录， 不得涉及任何中介人并应遵守直接的书面协议， 其中包括保密性和利益冲突。 相关公告机构应对分包商完成的任务承担全部责任。 Any subcontracting or consultation of external personnel shall be properly documented, shall not involve any intermediaries and shall be subject to a written agreement covering, among other things, confidentiality and conflicts of interest. The notified body in

question shall take full responsibility for the tasks performed by subcontractors.

3.4.3. 若由分包商或外部专家开展符合性评估（特别是有关异常性、侵入性和植入性的器械和技术），相关公告机构自身应在指定的各产品领域具有足够能力以引导整体符合性评估，以核实专家意见的恰当性和有效性并做出认证决议。 Where subcontractors or external experts are used in the context of a conformity assessment, in particular regarding novel, invasive and implantable devices or technologies, the notified body in question shall have internal competence in each product area for which it is designated that is adequate for the purpose of leading the overall conformity assessment, verifying the appropriateness and validity of expert opinions and making decisions on certification.

3.5. 监测能力、培训和经验交流 Monitoring of competences, training and exchange of experience

3.5.1. 公告机构应制定程序，对符合性评估活动中涉及的所有内部和外部人员和分包商的能力，符合性评估活动和绩效进行初步评估和持续监测。The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel, and subcontractors, involved in conformity assessment activities.

3.5.2. 公告机构应定期审查其人员的能力，确定培训需求，并制定培训计划，以保持个体人员所需的资格和知识水平。审查应至少核实人员： Notified bodies shall review at regular intervals, the competence of their personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel. That review shall at a minimum, verify that personnel:

- 联盟和有关器械的国家法律，相关的协调标准，CS，指导性文件，和根据第 1.6 节的协调活动结果；are aware of Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities referred to in Section 1.6; and
- 参与第 3.1.2 节所述的内部交流经验和持续培训及教育计划。take part in the internal exchange of experience and the continuous training and education programme referred to in Section 3.1.2.

4. 程序要求 PROCESS REQUIREMENTS

4.1. 总则 General

公告机构应有指定的各符合性评估活动的文件化流程和足够详细的程序，包括从预申请活动到决议及监督的各个步骤，并在必要时考虑到器械的相应特性。The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities up to decision making and surveillance and taking into account, when necessary, the respective specificities of the devices.

应符合第 4.3、4.4、4.7 和 4.8 节所述的要求以作为公告机构的内部活动一部分，且不得转包。The requirements laid down in Sections 4.3, 4.4, 4.7 and 4.8 shall be fulfilled as part of the internal activities of notified bodies and shall not be subcontracted.

4.2. 公告机构报价和预申请活动 Notified body quotations and pre-application activities

公告机构应 The notified body shall:

(a) 发布公开可用的申请程序说明，以便制造商通过说明获得公告机构认证。该说明应包括提交文件和任何相关信函可接受的语言； publish a publicly available description of the application procedure by which manufacturers can obtain certification from it. That description shall include which languages are acceptable for submission of documentation and for any related correspondence;

(b) 记录与特定符合性评估活动所收取的费用以及与其器械评估活动相关的任何其他财务状况； have documented procedures relating to, and documented details about, fees charged for specific conformity assessment activities and any other financial conditions relating to notified bodies' assessment activities for devices;

(c) 有关其符合性评估服务广告的书面程序。这些书面程序应确保广告或促销活动绝不暗示或可能导致推断其符合性评估将为制造商提供更早的市场准入，或者比其他指定机构更快、更容易或更不严格； have documented procedures in relation to advertising of their conformity assessment services. Those procedures shall ensure that advertising or promotional activities in no way imply or are capable of leading to an inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than that of other notified bodies;

(d) 有文件化的程序，要求审查预申请的信息，包括在本法规所涵盖产品的初步验证及其分类，然后向制造

商发出关于特定符合性评估的报价； have documented procedures requiring the review of pre-application information, including the preliminary verification that the product is covered by this Regulation and its classification, prior to issuing any quotation to the manufacturer relating to a specific conformity assessment; and

(e) 确保与本法规所涵盖的符合性评估活动有关的所有合同均直接在制造商与公告机构之间建立，而非与任何其他组织建立。 ensure that all contracts relating to the conformity assessment activities covered by this Regulation are concluded directly between the manufacturer and the notified body and not with any other organisation.

4.3. 申请审查与合同 Application review and contract

公告机构应要求（申请人）提供由制造商或授权代表签署的正式申请，其中应包含相关符合性评估附录 IX 至 XI 要求的所有信息和制造商的声明。 The notified body shall require a formal application signed by a manufacturer or an authorised representative containing all of the information and the manufacturer's declarations required by the relevant conformity assessment as referred to in Annexes IX to XI.

公告机构与制造商之间的合同应采取双方签署的书面协议的形式。其应由公告机构保存。本合同应有明确的条款和条件，并包含使公告机构能够按照本法规的要求行事的义务，包括制造商有义务通知公告机构警戒报告，公告机构有权暂停、 限制或取消发放的证书以及公告机构履行其信息义务的职责。 The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations.

公告机构应有关于审查申请的书面程序，以便处理： The notified body shall have documented procedures to review applications, addressing:

(a) 有关在请求批准下，在相应附录中所述的符合性评估程序要求的申请的完整性， the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,

(b) 按照器械及其相应的分类对这些申请所涉及的产品进行资格验证， the verification of the qualification of products covered by those applications as devices and their respective classifications,

(c) 申请人选择的符合性评估程序是否适用于本法规规定的有关器械， whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,

(d) 公告机构根据其委任来审核申请表的能力，以及 the ability of the notified body to assess the application based on its designation, and

(e) 充足和适当资源的可用性。 the availability of sufficient and appropriate resources.

每次申请审查的结果均应记录在案。 拒绝或撤销申请应通知第 57 条所述的电子系统， 其他指定机构应当有权访问相关数据。 The outcome of each review of an application shall be documented. Refusals or withdrawals of applications shall be notified to the electronic system referred to in Article 57 and shall be accessible to other notified bodies.

4.4. 资源分配 Allocation of resources

公告机构应有文件化程序，以确保所有符合性评估活动由经过适当授权和合格的人员进行，这些人员应具有足够的经验以对需要进行符合性评估的器械、系统和过程以及相关文档进行评估。 The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and

related documentation that are subject to conformity assessment.

对于各应用，公告机构应确定所需资源，并指定某个人负责确保各应用的评估都根据相关程序进行并确保适当资源（包括人员在评估任务中的可用性）。作为符合性评估一部分进行所需的任务分配以及随后对此分配所做的任何更改都应记录在案。 For each application, the notified body shall determine the resources needed and identify one individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment. The allocation of tasks required to be carried out as part of the conformity assessment and any changes subsequently made to this allocation shall be documented.

4.5. 符合性评估活动 Conformity assessment activities

4.5.1 总则 General

公告机构及其人员应进行具有最高专业素质的符合性评估活动，并具备具体领域必要的技术和科学能力。 The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.

公告机构应具有足够的专业知识、设施和详细的文件化程序，以有效地进行相关公告机构指定的符合性评估活动，同时考虑到附录 IX 至 XI 中列出的具体要求，尤其是以下全部要求： The notified body shall have expertise, facilities and documented procedures that are sufficient to effectively conduct the conformity assessment activities for which the notified body in question is designated, taking account of the relevant requirements set out in Annexes IX to XI, and in particular all of the following requirements:

- 适当规划各项目的行为； appropriately plan the conduct of each individual project,
- 应确保所组成的评估小组有相关技术经验以及持续的客观性和独立性，并规定在适当的时间轮换评估小组成员， ensure that the composition of the assessment teams is such that there is sufficient experience in relation to the technology concerned, and that there is continuous objectivity and independence, and to provide for rotation of the members of the assessment team at appropriate intervals,
- 指定确定符合性评估活动完成时限的理由， specify the rationale for fixing time limits for completion of conformity assessment activities,
- 评估制造商的技术文件和为满足附录 I 所列要求而采用的解决方案， assess the manufacturer's technical documentation and the solutions adopted to meet the requirements laid down in Annex I,
- 审查制造商有关临床前评估的程序和文件， review the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects,
- 审查制造商有关临床评价的程序和文件， review the manufacturer's procedures and documentation relating to clinical evaluation,
- 论述制造商风险管理程序及其临床前和临床评价的评价与分析之间的借口，藉此评估其证实符合附录 I 要求的相关性， address the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and to evaluate their relevance for the demonstration of conformity with the relevant requirements in Annex I,
- 执行附件 IX 第 5.2 至 5.4 节所述的“具体程序” carry out the specific procedures referred to in Sections 5.2 to 5.4 of Annex IX,
- 在器械分成 IIa 或 IIb 类的情况下， 评估选定的器械技术文件， in the case of class IIa or class IIb devices, assess the technical documentation of devices selected on a representative basis,
- 计划和定期进行适当的监督审核和评估，执行或要求进行某些测试，以验证质量管理体系的正常运作，

并进行未事先通知的现场审核, plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced on site audits,

- 若涉及器械采样以验证制造的器械符合技术文件, 此类要求应在采样前定义相关的采样标准和测试程序, relating to the sampling of devices, verify that the manufactured device is in conformity with the technical documentation; such requirements shall define the relevant sampling criteria and testing procedure prior to sampling,
- 评估和验证制造商的活动是否符合相关附录的要求。 evaluate and verify a manufacturer's compliance with relevant Annexes.

公告机构必要时应考虑可用的 CS（通用规范）、指导和最佳的实践文件和协调标准，即使制造商没有声明法规符合性。 The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.

4.5.2 质量管理体系审核 Quality management system auditing

(a) 作为质量管理体系评估的一部分，公告机构应在审计之前根据其书面程序： As part of the assessment of the quality management system, a notified body shall prior to an audit and in accordance with its documented procedures:

- 根据相关符合性评估附录提交的文件进行评估并建立审核计划。 该计划应清楚地显示完全覆盖制造商的质量管理体系所需的评估活动数量及顺序，并确定其是否符合本法规的要求, assess the documentation submitted in accordance with the relevant conformity assessment Annex, and draw up an audit programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,
- 识别各个生产场所之间的链接和责任分配，以及识别制造商的相关供应商和 /或分包商，并考虑是否需要对这些供应商或分包商或两者进行专门审计, identify links between, and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both
- 为审计计划中确定的每项审计明确界定审计的目标、标准和范围；并拟订一项审计计划, 以充分处理和考虑到所涉器械、技术和过程的具体要求, clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit, and draw up an audit plan that adequately addresses and takes account of the specific requirements for the devices, technologies and processes involved,
- 对于 IIa 和 IIb 类器械， 制定并保持最新的计划以评定附录 II 和 III 所述的技术文件， 该文档涉及制造商申请所包含的这些范围的器械。该计划应确保证书所涵盖的所有器械在证书有效期内进行抽样， draw up and keep up to date, for class IIa and class IIb devices, a sampling plan for the assessment of technical documentation as referred to in Annexes II and III covering the range of such devices covered by the manufacturer's application. That plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate, and
- 选择和指派适当的合格授权人员进行个人审计。 应清楚地定义和记录团队成员各自的职位、 职责和权限。 select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.

(b) 依照制定的审计计划，公告机构应根据其书面程序： Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures

- 审计制造商的质量管理体系， 以便验证所涵盖的器械符合本规定的相关规定， 本规定适用于从设计到最后质量控制直至持续监督的每一个阶段，并应确定是否达到本法规的规定， audit the manufacturer's quality management system, in order to verify that the quality management system ensures that the devices covered conform to the relevant provisions of this Regulation which apply to devices at every stage, from design through final quality control to ongoing surveillance, and shall determine whether the requirements of this Regulation are met,
- 根据相关技术文件， 确定制造商是否符合相关符合性评估附录中所述的要求， 并审查和审核制造商的过程和子系统，特别是： based on relevant technical documentation and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems, in particular for
  - 设计和开发， design and development,
  - 生产过程控制 production and process controls, ,
  - 产品文档， product documentation,
  - 采购控制， 包括购买器械的检验， purchasing controls including verification of purchased devices,
  - 矫正和预防措施，包括上市后监管；和 corrective and preventive actions, including for post-market surveillance, and
  - PMCF

  并审查和审核制造商通过的要求和规定，包括与履行附件 I 所载的一般安全和性能要求有关的要求和规定。 and review and audit requirements and provisions adopted by the manufacturer, including those in relation to fulfilling the general safety and performance requirements set out in Annex I.

  应对文档进行抽样，以发现与器械的预期使用相关的风险、制造技术的复杂性、生产器械的范围和类别以及任何可用的上市后监控信息， The documentation shall be sampled in such a manner as to reflect the risks associated with the intended use of the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information,
- 若尚未被审核计划覆盖， 当成品器械的法规符合性受到多个供应商活动的显著影响时， 尤其是制造商不能证明其对供应商拥有足够的控制权时， 则将对制造商的供应商场所进行流程控制审核。 if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,
- 根据既抽样计划进行技术文件的评估，并考虑本附录第 4.5.4 和 4.5.5 节的临床前和临床评价。 conduct assessments of the technical documentation based on its sampling plan and taking account of Sections 4.5.4. and 4.5.5. for pre-clinical and clinical evaluations, and
- 依照本法规的要求，并依照相关标准或由 MDCG 编订或通过的最佳实践文件，公告机构应确保审计结果进行适当且一致的分类。 the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards, or with best practice documents developed or adopted by the MDCG.

4.5.3 产品验证 Product verification

技术文件评估 Assessment of the technical documentation

为评估依据附录 IX 第 II 章而执行的技术文件，公告机构应具有足够的专业知识和设施，并提供详细书面程序：

For assessment of the technical documentation conducted in accordance with Chapter II of Annex IX, notified bodies shall have sufficient expertise, facilities and documented procedures for:

- 具有合适资格和授权的人员的委任，以进行各个方面的检查，例如器械使用、生物相容性、临床评价、风险管理、杀菌等；the allocation of appropriately qualified and authorised personnel for the examination of individual aspects such as use of the device, biocompatibility, clinical evaluation, risk management, and sterilisation, and
- 评估是否符合本法规规定的设计并考虑第 4.5.4 至 4.5.6 节规定。该评估应包括检验进货、制程中和最终检查的执行情况和结果。若需要进一步测试或其他证据，以评估其是否符合本法规的要求，相关公告机构应当实施与器械有关的适当物理或实验室测试，或要求制造商实施这些测试。 the assessment of conformity of the design with this Regulation, and for taking account of Sections 4.5.4. to 4.5.6. That assessment shall include examination of the implementation by manufacturers of incoming, in-process and final checks and the results thereof. If further tests or other evidence is required for the assessment of conformity with the requirements of this Regulation, the notified body in question shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

型式检验 Type-examinations

公告机构应具有用于器械型式检验（按照附录 X 进行）的书面程序、充分专业知识和设施，包括以下能力：

The notified body shall have documented procedures, sufficient expertise and facilities for the type-examination of devices in accordance with Annex X including the capacity to:

- 考虑本附录第 4.5.4 到 4.5.6 节，检查和评估技术文件，并验证该类型已按照符合技术文件的要求制造；examine and assess the technical documentation taking account of Sections 4.5.4. to 4.5.6., and verify that the type has been manufactured in conformity with that documentation;
- 建立一个测试计划，确定公告机构需要测试或在其职责范围之内的所有相关和关键参数； establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility;
- 记录选择这些参数的理由， document its rationale for the selection of those parameters;
- 进行适当的检验和测试，以验证制造商采用的解决方案是否满足附录 I 规定的通用安全与性能要求。此种检验和测试应该包括所有必要的测试，以验证该制造商实际已选择使用的相关标准， carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements set out in Annex I. Such examinations and tests shall include all tests necessary to verify that the manufacturer has in fact applied the relevant standards it has opted to use;
- 若公告机构不直接进行这些测试，则需要与申请人协定必要测试的执行地点， agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body; and
- 对测试结果承担全部责任。若其由具有资质以及独立于制造商的法规符合性评估机构颁发，应可考虑制造商提交的测试报告。 assume full responsibility for test results. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

通过检查和测试每一件产品来进行验证, 公告机构应该： Verification by examination and testing of every product The notified body shall:

(a) 具有记录程序、 足够的专业知识和设施, 已根据附录 XI 第 B 部分, 通过检查和测试每一件产品来进行验证。 have documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product in accordance with Part B of Annex XI;

(b) 建立一个测试计划, 确定公告机构需要测试或在其职责范围之内的所有相关和关键参数, 以便： establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:

- 对于 IIb 类器械：验证器械是否符合欧盟型式检验证书说明的类型, 及本法规中适用的要求。 verify, for class IIb devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,
- -对于 IIa 类器械：确认是否符合附录 II 和 III 所述的技术文件，及本法规中适用于这些器械的要求, 并记录其对这些参数的选择理由； confirm, for class IIa devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices;

(c) 记录选择 (b)点所述参数的理由； document its rationale for the selection of the parameters referred to in point (b);

(d) 有文件程序进行适当的评估和测试，以根据附录 XI 第 15 节的规定，通过检查和测试每一件产品，验证器械符合法规要求。 have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of this Regulation by examining and testing every product as specified in Section 15 of Annex XI;

(e) 若公告机构自身不执行这些必要测试，则应具有与申请人达成执行这些必要测试的时间和地点有关的书面程序协议； have documented procedures providing for the reaching of an agreement with the applicant concerning when and where necessary tests that are not to be carried out by the notified body itself are to be performed; and

(f) 按照书面程序，对测试结果承担全部责任。可考虑制造商提交的测试报告，若它们由具有资质以及独立于制造商的法规符合性评估机构颁发。 assume full responsibility for test results in accordance with documented procedures; test reports submitted by the manufacturer shall only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

4.5.4 临床前评估的评定 Pre-clinical evaluation assessment

公告机构应有文件程序，以对制造商进行有关临床前评价方面的程序和文件的审查。公告机构应检查、验证和确认制造商的程序和文件充分解决以下问题： The notified body shall have documented procedures in place for the review of the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:

(a) 计划、执行、评估、报告，并在适当时更新临床前评价，特别是 the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, in particular of

-科学的临床前文献检索；和 the scientific pre-clinical literature search, and

-实验室测试、 模拟使用测试、 计算机模拟、 使用动物模型的临床前试验 the pre-clinical testing, for example laboratory testing, simulated use testing, computer modelling, the use of animal models,

(b) 身体接触的性质和持续时间, 和特定的相关生物风险。 the nature and duration of body contact and the specific associated biological risks,

(c) 与风险管理程序的接口；和 the interface with the risk management process, and

(d) 可用的临床前数据及其相关性的评价和分析, 以证实符合附录 I 的有关要求。 the appraisal and analysis of the available pre-clinical data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I.

公告机构对临床前评价程序和文件的评估，应说明文献检索结果和所有批准、验证和进行的测试、得出的结论，并应通常考虑替代材料和物质，及成品器械的包装、稳定性 /保质期。若制造商没有进行新的测试或偏离了程序，相关公告机构应严格审查制造商提出的理由。 The notified body's assessment of pre-clinical evaluation procedures and documentation shall address the results of literature searches and all validation, verification and testing performed and conclusions drawn, and shall typically include considering the use of alternative materials and substances and take account of the packaging, stability, including shelf life, of the finished device. Where no new testing has been undertaken by a manufacturer or where there are deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.

4.5.5 临床评价的评估 Clinical evaluation assessment

公告机构应当有文件程序，规定制造商的临床评价程序和文件评估，包括初始符合性评估，以及进行中评估。

公告机构应检查、验证和确认制造商的程序和文件充分解决了以下问题： The notified body shall have documented procedures in place relating to the assessment of a manufacturer's procedures and documentation relating to clinical evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that manufacturers' procedures and documentation adequately address:

- 根据附录 XIV 来规划、 执行、 评估、 报告和更新临床评价, the planning, conduct, assessment, reporting and updating of the clinical evaluation as referred to in Annex XIV,
- 上市后监管和 PMCF， post-market surveillance and PMCF,
- 与风险管理流程的相互作用, the interface with the risk management process,
- 可用数据及其相关性分析和评估，以便证明符合附录 I 中相关要求, the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements in Annex I, and
- 关于临床证据和制定临床评价报告得出的结论 the conclusions drawn with regard to the clinical evidence and drawing up of the clinical evaluation report.

第一段所述程序应包含到现有 CS、指导和最佳规程文件。 These procedures referred to in the first paragraph shall take into consideration available CS, guidance and best practice documents.

根据附录 XIV，公告机构临床评价的评估应包括： The notified body's assessment of clinical evaluations as referred to in Annex XIV shall cover:

- 制造商指定的预期用途，及其定义的器械声明, the intended use specified by the manufacturer and claims for the device defined by it,
- 临床评价的规划, the planning of the clinical evaluation,
- 文献检索方法, the methodology for the literature search
- 从文献检索得到的相关文件, relevant documentation from the literature search,
- 临床研究, the clinical investigation,
- 验证声称与其他相关器械等效的陈述，等效性证明，同等和类似器械的适用性和结论, validity of

equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

- 上市后监管和 PMCF， post-market surveillance and PMCF,
- 临床评价报告， the clinical evaluation report, and
- 不执行临床研究或 PMCF 的理由 justifications in relation to non-performance of clinical investigations or PMCF.

关于从临床评价包含的临床研究中得到的临床数据，依据提交的批准临床研究计划，相关公告机构应确保制造商得出的结论是有效的。 In relation to clinical data from clinical investigations included within the clinical evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved clinical investigation plan.

公告机构应确保临床评价充分说明了附录 I 规定的相关安全与性能要求， 这与按照附录 XIV 执行的风险管理、要求应适当一致，还应确保其适当反映在器械提供的信息中。 The notified body shall ensure that the clinical evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements, that it is conducted in accordance with Annex XIV and that it is appropriately reflected in the information provided relating to the device.

4.5.6 “特殊流程” Specific Procedures

针对附录 IX 的第 5 和 6 节，附录 X 的第 6 节和附录 XI 的第 16 节委任给公告机构的流程， 公告机构应有相应的书面程序、 足够的专业知识和设施。 The notified body shall have documented procedures, sufficient expertise and facilities for the procedures referred to in Sections 5 and 6 of Annex IX, Section 6 of Annex X and Section 16 of Annex XI, for which they are designated.

若要利用第 722/2012 号法规中所述的动物源组织或细胞制造的器械， 如 TSE 易危种， 公告机构应有文件程序，遵守以上法规的要求，并应编制总结评价报告，提交至有关主管机构。 In the case of devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from TSE susceptible species, as referred to in Regulation (EU) No 722/2012, the notified body shall have documented procedures in place that fulfil the requirements laid down in that Regulation, including for the preparation of a summary evaluation report for the relevant competent authority.

4.6. 报告 Reporting

公告机构应： The notified body shall:

- 确保记录了法规符合性评估中的所有步骤，使得这些评估结论明确以及证明其符合本法规要求，为未参与评估的人提供客观证据，如指定主管机构的工作人员， ensure that all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can represent objective evidence of such compliance to persons that are not themselves involved in the assessment, for example personnel in designating authorities,
- 确保足以提供清晰审核线索的质量管理体系审核记录可用， ensure that records that are sufficient to provide a discernible audit trail are available for quality management system audits,
- 在临床评估的评定报告中清楚地记录对临床评价的评估结论， clearly document the conclusions of its assessment of clinical evaluation in a clinical evaluation assessment report, and
- 对各具体项目， 提供一份详细报告， 该报告应基于标准格式， 包含 MDCG 决议的最少一组元素。 for each specific project, provide a detailed report which shall be based on a standard format containing a minimum set of elements determined by the MDCG.

公告机构报告应： The report of the notified body shall:

- 清楚地记录其评估结果，对制造商是否符合本法规要求给出明确结论， clearly document the outcome of its assessment and draw clear conclusions from the verification of the manufacturer's conformity with the requirements of this Regulation,
- 公告机构给出最终审查建议和最终决议；此建议应由公告机构的负责人明确签字， make a recommendation for a final review and for a final decision to be taken by the notified body; this recommendation shall be signed off by the member of personnel responsible in the notified body, and
- 提供给相关制造商。 be provided to the manufacturer in question.

4.7. 最终审查 Final review

在做出最后决定之前，公告机构应确保： The notified body shall prior to making a final decision:

- 对偶于负责特定项目的最终审查和决定工作的人员应慎重选派，且不可与评估执行人员为同一人， ensure that the personnel assigned for the final review and decision-making on specific projects are appropriately authorised and are different from the personnel who have conducted the assessments,
- 验证做出决定所需的报告和支持文件，包括有关评估过程中对所申请范围内容提出的不符合项， verify that the report or reports and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and
- 验证是否存在任何悬而未决的、 阻止欧盟证书签发的不符合项。 verify whether there are any unresolved non-conformities preventing issuance of a certificate.

4.8. 决议和认证 Decisions and Certifications

公告机构应当有关于决策的文件程序，包括签发、吊销、限制和撤销证书的责任分配。这些程序应包括根据本法规第 V 章规定的通知要求。这些程序应允许相关公告机构： The notified body shall have documented procedures for decision-making including as regards the allocation of responsibilities for the issuance, suspension, restriction and withdrawal of certificates. Those procedures shall include the notification requirements laid down in Chapter V of this Regulation. The procedures shall allow the notified body in question to:

- 基于评估文件和其他可获得的信息，判断是否满足法规要求， decide, based on the assessment documentation and additional information available, whether the requirements of this Regulation are fulfilled,
- 基于其对临床评价和风险管理的评估结果， 判断 PMS 计划（包括 PMCF）是否充分， decide, based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,
- 判断是否满足具体的里程碑要求，以供公告机构对最新临床评价进一步审查， decide on specific milestones for further review by the notified body of the up to date clinical evaluation,
- 判断是否需要定义特定的条件或条款， decide whether specific conditions or provisions need to be defined for the certification,
- 基于新颖性、风险分级、临床评价和器械风险分析的结果，决议一个不超过五年的认证周期， decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years,

- 清楚地记录决议和审批的步骤，包括相关负责人员的签字批准，clearly document decision making and approval steps including approval by signature of the members of personnel responsible,

- 清楚地记录决议通讯的职责和机制，特别是，若证书的最后签署者与决议者不同或不符合第 3.2.7 节中规定的要求，clearly document responsibilities and mechanisms for communication of decisions, in particular, where the final signatory of a certificate differs from the decision maker or decision makers or does not fulfil the requirements laid down in Section 3.2.7,

- 按照附录 XII 规定的最低要求签发证书，有效期不超过五年，并应说明是否有与认证相关的特定条件或限制，issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification,

- 只为申请人颁发证书，并且不得颁发覆盖多个实体的证书，issue a certificate or certificates for the applicant alone and shall not issue certificates covering multiple entities, and

- 确保将评估结果和最终决议通知制造商，并输入到第 57 条所述的电子系统。ensure that the manufacturer is notified of the outcome of the assessment and the resultant decision and that they are entered into the electronic system referred to in Article 57.

4.9. 变更和修改 Changes and modifications

关于信息责任和变化的评估，公告机构与制造商之间应该具有适当的书面程序和合同安排：The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to:

- 经批准的质量管理体系或覆盖的产品范围，the approved quality management system or systems or to the product-range covered,

- 经批准的器械设计，the approved design of a device,

- 预期器械用途或对器械提出的要求，the intended use of or claims made for the device,

- 经批准的器械类型，the approved type of a device, and

- 纳入器械或用于制造器械的任何物质，并且根据第 4.56 节，受到“具体程序”的制约。any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6.

第一段所述程序和合同协议应包括检查第一段所述变更的意义过程。The procedures and contractual arrangements referred to in the first paragraph shall include measures for checking the significance of the changes referred to in the first paragraph.

根据其书面程序，相关公告机构应：In accordance with its documented procedures, the notified body in question shall:

- 确保制造商在批准计划之前，第一段所述变更提交计划以及与此类变更相关的信息，ensure that manufacturers submit for prior approval plans for changes as referred to in the first paragraph and relevant information relating to such changes,

- 对提议的变化进行评估，并验证做出这些变化之后，质量管理体系或器械的设计或类型是否仍符合本法规的要求，assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of this Regulation, and

- 将其决议通知制造商并提供一份报告或补充报告 （视情况而定），其中应包含其评估 /审核的合理结论。 notify the manufacturer of its decision and provide a report or as applicable a supplementary report, which shall contain the justified conclusions of its assessment.

4.10. 监管活动和认证后监控 Surveillance activities and post-certification monitoring

公告机构应具有书面程序： The notified body shall have documented procedures:

- 确定制造商如何以及何时执行监管活动。这些程序应包括，对制造商以及实时的分包商和供应商，进行突击现场审核，实时产品测试，并监控制造商的任何条件是否符合相关的认证决议，例如，在特定的时间间隔，临床数据的更新， defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals,
- 用于筛选相关来源的科学和临床数据，及其型号范围内相关的上市后信息。在规划和开展监管活动时，应考虑此类信息， for screening relevant sources of scientific and clinical data and post-market information relating to the scope of their designation. Such information shall be taken into account in the planning and conduct of surveillance activities, and
- 根据第 92（2）条审查可获取的警戒数据，以便估计其对现有证书有效性的影响（如有） 。评估的结果和做出的任何决议， 应全面记录。 to review vigilance data to which they have access under Article 92(2) in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.

相关公告机构收到来自制造商或主管机构的警戒案件信息之后，应对以下应用选项做出决议： The notified body in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide which of the following options to apply:

- 无需采取行动，因为警戒案件与授权认证无清晰关联， not to take action on the basis that the vigilance case is clearly not related to the certification granted,
- 观察制造商和主管机构活动，制造商研究结果以便确定授权认证是否遭受威胁或是否已执行适当的纠正措施， observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,
- 执行特殊监管措施，例如文件审查、临时通知或突击的审核、产品测试，以确定授权的认证是否遭受威胁， perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and product testing, where it is likely that the certification granted is at risk,
- 加大监管审核的频率， increase the frequency of surveillance audits,
- 在对制造商的下一次审核中，审查特定产品或工艺，或 review specific products or processes on the occasion of the next audit of the manufacturer, or
- 采取任何其他相关的措施。 take any other relevant measure.

关于制造商的监管审核，公告机构应具有书面程序： In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:

- 对制造商的监管审核至少每年进行一次，并且其规划和实施应符合第 4.5 节中的相关要求， conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in Section 4.5,

- 确保充分地评估制造商的文件和应用，包括警戒规定和上市后监管和 PMCF， ensure adequate assessment of the manufacturer's documentation on, and application of the provisions on, vigilance, the post-market surveillance, and PMCF,
- 在审计期间，根据预定义的采样标准和测试程序，采样并测试器械和技术文件，以确保制造商持续采用经批准的质量管理体系， sample and test devices and technical documentation, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,
- 确保制造商符合本法规中相关附录所规定的文件和信息责任，并且其程序考虑到推行质量管理体系的最佳规程， ensure that the manufacturer complies with the documentation and information obligations laid down in the relevant Annexes and that its procedures take into account best practices in the implementation of quality management systems,
- 确保制造商以正确的方式使用质量管理体系或器械审批， ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,
- 收集足够多的信息，以确定质量管理体系是否持续符合本法规的要求， gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,
- 若检测到不符合性，应要求制造商进行整改，当预防性措施可用时，采取纠正措施，并且 ask the manufacturer, if non-conformities are detected, for corrections, corrective actions and, where applicable, preventive actions, and
- 必要时，对相关证书施加特别的限制或中止或撤销它。 where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw it.

若归类为认证的条件之一， 该公告机构应： The notified body shall, if listed as part of the conditions for certification:

- 基于上市后监管、 PMC 和有关器械治疗和类似器械的临床文献，开展制造商最新临床评价的深入审查， conduct an in-depth review of the clinical evaluation as most recently updated by the manufacturer based on the manufacturer's post-market surveillance, on its PMCF and on clinical literature relevant to the condition being treated with the device or on clinical literature relevant to similar devices,
- 清楚地记录本次深度审查的结果，并解决制造商的任何具体问题或施加任何具体情况， clearly document the outcome of the in-depth review and address any specific concerns to the manufacturer or impose any specific conditions on it, and
- 确保最新的临床评价适当地反映在使用说明及安全与性能数据总结中。 ensure that the clinical evaluation as most recently updated, is appropriately reflected in the instructions for use and, where applicable, the summary of safety and performance.

4.11 再认证 Re-certification

关于再认证审查和证书的续办，公告机构应具有适当的书面程序。对批准的质量管理体系或欧盟 - 技术文件，评估证书或欧盟型式检验证书的再认证，至少应每五年进行一次。 The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

对于欧盟技术文件评估的续办证书和欧盟型式检验证书，公告机构应具有相关的书面程序，这些程序要求制造商对做出的更改提交一份总结以及该器械的科学发现，包括： The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and

those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) 对原始批准器械做出的更改，包括尚未通知的更改， all changes to the originally approved device, including changes not yet notified,

(b) 从上市后监管获取的经验， experience gained from post-market surveillance

(c) 从风险管理获取的经验， experience from risk management,

(d) 从更新证据， 使之符合附录 I 规定的通用安全与性能要求获取的经验， experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) 临床评价审查的经验，包括任何临床研究的结果和 PMCF， experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,

(f) 要求、器械零部件、科学或监管环境的变化， changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) 已经采用的或新 （协调） 标准， CS 或同等文件的变化， changes to applied or new harmonised standards, CS or equivalent documents, and

(h) 医疗、科学和技术知识的变化，例如： changes in medical, scientific and technical knowledge, such as:

- 新疗法， new treatments,
- 测试方法的变化， changes in test methods
- 材料和零部件的新科学发现，包括生物相容性， new scientific findings on materials and components, including findings on their biocompatibility,
- 从类似器械研究获取的经验， experience from studies on comparable devices,
- 登记人 /登记数据， data from registers and registries,
- 同类器械的临床研究经验。 experience from clinical investigations with comparable devices.

公告机构应有文件程序， 评估第二段所述的信息， 并应特别注意自上一次认证或再认证以来的上市后监管和 PMCF 活动的临床数据， 包括适当更新制造商的临床评价报告。 The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

对于再认证决议，相关公告机构应采用与原始证书决议相同的方法和原则。如必要，应建立独立再认证的形式，并考虑到上述步骤， 例如， 应用和应用审查。 For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

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附录 VIII ANNEX VIII

分类规则 CLASSIFICATION RULES

第 I 章 CHAPTER I

分类规则的具体定义 DEFINITIONS SPECIFIC TO CLASSIFICATION RULES

1. 使用持续时间 DURATION OF USE

1.1. “短暂”是指预期正常连续使用不超过 60 分钟。‘Transient’ means normally intended for continuous use for less than 60 minutes.

1.2. “短期”是指预期正常连续使用 60 分钟到 30 天之间。‘Short term’ means normally intended for continuous use for between 60 minutes and 30 days.

1.3. “长期”是指预期正常连续使用超过 30 天。‘Long term’ means normally intended for continuous use for more than 30 days.

2. 侵入性器械和有源器械 INVASIVE AND ACTIVE DEVICES

2.1. “身体孔口”是指身体的任何天然开口，以及眼球的外表面，或者任何永久性人工开口，如造口。‘Body orifice’ means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

2.2. “外科侵入性器械”是指 ‘Surgically invasive device’ means:

(a) 侵入性器械从身体表面穿透进身体，包括外科手术时通过身体孔口的粘膜穿透； an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and

(b) 一种不通过身体孔口穿透的器械 a device which produces penetration other than through a body orifice.

2.3. “可重复使用的外科器械”是指通过切割、钻、锯、刮、削、夹、收缩、剪切或类似方式用于外科使用的器械，不连接到任何有源医疗器械，制造商预期可通过适当的处理之后再次使用，如实施清洁、消毒和灭菌。‘Reusable surgical instrument’ means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

2.4. “有源治疗器械”是指任何有源器械，无论是单独使用或与其他器械联合使用，以支持、更改、替换或恢复生物学功能或结构，以期疾病、损伤或残障得到治疗或缓解。‘Active therapeutic device’ means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability.

2.5. “用于诊断和监测的有源器械”是指任何有源器械，无论是单独使用或与其他器械组合使用，用于为检测、诊断、监测或治疗生理病症、健康状况、疾病或先天畸形。‘Active device intended for diagnosis and monitoring’ means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

2.6. “中央循环系统”是指以下血管：肺动脉、升主动脉、弓主动脉、动脉分岔的降主动脉、冠状动脉、颈总动脉、颈外动脉、颈内动脉、脑动脉、头臂干、心静脉、肺静脉、上腔静脉、下腔静脉。‘Central circulatory system’ means the following blood vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.

2.7. “中枢神经系统”是指脑、脑膜和脊髓。 ‘Central nervous system’ means the brain, meninges and spinal cord.

2.8. “损伤的皮肤或粘膜”是指皮肤或粘膜呈现病理变化或带来疾病或伤口变化的区域。 ‘Injured skin or mucous membrane’ means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound.

第 II 章

实施规则 IMPLEMENTING RULES

3.1. 分类规则的使用应基于器械的预期目的。 Application of the classification rules shall be governed by the intended purpose of the devices.

3.2. 若相关器械将与其他器械共同使用，分类规则应分别适用于各器械。医疗器械和附录 XVI 所列产品的附件，应根据其自身因素进行分类，独立于它们所适用的器械。 If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories for a medical device and for a product listed in Annex XVI shall be classified in their own right separately from the device with which they are used.

3.3. 驱动某一器械或影响器械使用的软件，应与该器械归为同一类别。 Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

若该软件独立于任何其他器械，则应按照其本身进行分类。 If the software is independent of any other device, it shall be classified in its own right.

3.4. 若该器械并不预期单独或主要作用于身体的特定部位，则它应基于其最关键的特定用途来考虑和分类。 If the device is not intended to be used solely or principally in a specific part of the body, it shall be considered and classified on the basis of the most critical specified use.

3.5 基于器械的预期目的，若多个规则（或同一规则的多个子规则）同时适用于同一器械，则应采用能带来更高分类等级的最严格规则和子规则。 If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

3.6. 依据第 1 节中所述的持续时间，持续使用是指：

In calculating the duration referred to in Section 1, continuous use shall mean:

(a) 使用相同器械的整个持续时间，而不考虑使用过程中的暂时中断，或有目的暂时移除，如器械的清洁或消毒。使用的中断或移除是否是临时性的，应根据中断使用或器械移除的这段期间之前和之后的使用持续时间来判断。 the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device. Whether the interruption of use or the removal is temporary shall be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed; and

(b) 器械累积使用，即制造商预期器械使用过程中会由另一相同型号迅速替换。 the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

3.7. 当器械本身提供相关疾病或病情的诊断时，或能够提供诊断的决议性信息时，器械可被认为允许提供直接诊断。

A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

第 III 章

分类规划 CLASSIFICATION RULES

4. 无创器械 NON-INV ASIVE DEVICES

4.1. 规则 **1** Rule 1

所有非侵入性器械归类为 I 类，除非下文列出的某条规则适用。 All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

4.2. 规则 **2** Rule 2

用于引导或储存血液、体液、细胞或组织、液体或气体，以便最终输注、施用或引入进入体内的所有非侵入器械归类为 IIa 类、 IIb 类或 III 类有源器械： All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

- 若其可连接至 IIa 类或更高类别的有源医疗器械， if they may be connected to a class IIa, class IIb or class III active device; or
- 若其用于输送或储存血液或其他体液或用于储存器官、器官的某个部分或身体细胞和组织，则归类为 IIb 类（血袋除外）。 if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

在所有其他情形下，此类器械均归类为 I 类。 In all other cases, such devices are classified as class I.

4.3. 规则 **3** Rule 3

所有用于更改人体组织或细胞、血液、其他体液或其他植入或注入体内的液体的生物或化学成分的非侵入性器械均归类为 IIb 类，除非该治疗包含过滤、 离心或气体交换、 加热，此类情形归类为 IIa 类。All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.

对于所有含某种物质或混合物质的非侵入性器械，若其用于体外直接接触从人体或人类胚胎取下体外使用的人体细胞、 组织或器官， 之后再植入或注入体内， 则归类为 III 类。 All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class III.

4.4. 规则 **4** Rule 4

对于所有接触受伤皮肤或粘膜的非侵入性器械按以下归类： All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:

- 若其作为机械屏障使用，或用于压缩或渗液吸收，则归类为 I 类； class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
- 若其主要用于伤及真皮且需要二期愈合治愈的皮肤或黏膜伤口，则归类为 IIb 类； class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;
- 在其他所有情形下， 均归类为 IIa 类, 包括主要用于管理受伤皮肤或粘膜微环境的器械； class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and
- 在其他所有情形下，均归类为 IIa 类。 class IIa in all other cases.

本规则亦适用于接触受伤粘膜的侵入性器械。 This rule applies also to the invasive devices that come into contact with injured mucous membrane.

5. 侵入性器械 INVASIVE DEVICES

5.1. 规则 5 Rule 5

除外科侵入性器械以外，所有不用于连接有源医疗器械或用于连接 I 类有源医疗器械且与身体孔口相关的侵入性器械： All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:

- 若其为短暂使用，则归类为 I 类， class I if they are intended for transient use;
- 若其为短期使用，则归类为 IIa 类，但用于咽部以上的口腔、耳鼓以外的耳道或鼻腔时除外，在此情形应下，应属于 I 类 class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and
- 若其为长期使用，则归类为 IIb 类，但用于咽部以上的口腔、耳鼓以外的耳道或鼻腔且不易通过粘膜吸收时除外， 在此情形应下， 应属于 IIa 类。 class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

除外科侵入性器械以外， 所有用于连接 IIa 类、 Iib 类或 III 类的有源器械， 且与身体孔口相关的侵入性器械均归类为 IIa 类。 All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

5.2. 规则 6 Rule 6

所有短暂使用的外科侵入性器械均归类为 IIa 类， 除非其： All surgically invasive devices intended for transient use are classified as class IIa unless they:

- 专门用于通过直接接触身体的某个部位，以控制、诊断、监测或纠正心脏或中央循环系统的缺陷，在此情形应下，应归类为 III 类； are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- 可重复使用的外科器械， 在此情形下， 应归类为 I 类；are reusable surgical instruments, in which case they are classified as class I;
- 专门用于直接接触心脏或中央循环系统或中央神经系统，在此情形下，应归类为 III 类； are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- 用于以电离辐射形式供应能量，在此情形下，应归类为 IIb 类；are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;
- 具有生物效应或能够被完全吸收或大部分被吸收， 在此情形下， 应归类为 IIb 类；have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or
- 用于通过传输系统的方法来施用医药产品，并且若考虑到应用方法，施用此类医药产品的执行方式存在潜在危险，在此情形下，应归类为 IIb 类。 are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

5.3 规则 7 Rule 7

所有短期使用的外科侵入性器械均归类为于 IIa 类，除非其： All surgically invasive devices intended for short-term

use are classified as class IIa unless they:

- 专门用于通过直接接触身体的某个部位，以控制、诊断、监测或纠正心脏或中央循环系统的缺陷，在此情形应下，应归类为 III 类； are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- 专门用于直接接触心脏或中央循环系统或中枢神经系统，在此情形下，应归类为 III 类； are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- 用于以电离辐射形式供应能量，在此情形下，应归类为 IIb 类；are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;
- 具有生物效应或能够被完全吸收或大部分被吸收，在此情形下，应归类为 III 类；have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;
- 用于在体内产生化学变化，但该器械放置在牙齿上除外，在此情形下，应归类为 IIb 类； are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or
- 用于施用药物时，在此情形下应归类为 IIb 类。 are intended to administer medicines, in which case they are classified as class IIb.

5.4. 规则 **8** Rule 8

所有植入式器械和长期外科侵入性器械均归类为 IIb 类，除非其： All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

- 放置在牙齿上，在此情形下，应归类为 IIa 类； are intended to be placed in the teeth, in which case they are classified as class IIa;
- 用于直接接触心脏或中央循环系统或中枢神经系统，在此情形下，应归类为 III 类；are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;
- 具有生物效应或能够被完全吸收或大部分被吸收，在此情形下，应归类为 III 类；have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;
- 用于在体内产生化学变化，但该器械放置在牙齿上除外，在此情形下，应归类为 III 类； are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;
- 用于施用医疗产品时，在此情形下，应归类为 III 类； are intended to administer medicinal products, in which case they are classified as class III;
- 为有源植入式器械或其相关附件，在此情形下，应归类 III 类； are active implantable devices or their accessories, in which cases they are classified as class III;
- 为乳房植入物或心脏修补网状织物， 在此情形下， 应归类 III 类；are breast implants or surgical meshes, in which cases they are classified as class III;
- 为完整或部分关节置换物， 在此情形下， 应归类 III 类，但辅助部件除外， 如螺钉、 楔、板和仪表； are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; o
- 为直接与脊柱接触的椎间盘置换植入物或为植入器械，在此情形下，应归类 III 类，但辅助部件除外，如

螺钉、楔、板和仪表。 r are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

6. 有源器械 ACTIVE DEVICES

6.1. 规则 9 Rule 9

用于注入或交换能量的所有有源治疗器械均归类 IIa 类，除非它们向 /从人体注入 /吸收能量或与人体交换能量的同时可能会造成危害，并考虑到能量应用的密度和部位，此类器械应归类 IIb 类。 All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

所有用于控制或监测有源治疗 IIb 类器械性能或用于直接影响此类器械性能的有源器械均归类 IIb 类。All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

所有针对治疗目的释放电离辐射的有源器械均归类 IIb 类，这其中包括控制或监测此类器械或直接影响其性能的器械。All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

所有用于控制、 监测或直接影响有源植入式器械性能的有源器械均归类 III 类。All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

6.2. 规则 10 Rule 10

用于诊断和监测的有源器械均归类 IIa 类： Active devices intended for diagnosis and monitoring are classified as class IIa:

- 若其用于提供可被人体吸收的能量，但用于通过可见光谱照亮患者身体的器械除外，在此情形下，应归类 I 类； if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
- 若其用于生成放射性药物的体内分布图像； if they are intended to image in vivo distribution of radiopharmaceuticals; or
- 若其用于直接诊断或监测重要生理过程，除非其专门用于监测重要生理参数，且这些参数变化性质可导致患者面临紧急危险，包括在患者面临紧急危险的临床情况下心脏功能、呼吸、中枢神经系统活动或诊断的变化，在此情形下，应归类 IIb 类。 if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

用于释放电离辐射和预期用于诊断或治疗放射的有源器械，包括介入放射器械以及控制或监测此类器械或直接影响其性能的器械，均归类 IIb 类。 Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

6.3. 规则 11 Rule 11

用于提供诊断或治疗目的决策信息的软件均归类 IIa 类，除非此类决策会导致以下影响： Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- 死亡或人员健康状况的不可逆恶化，在此情形下，应归类 III 类；death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- 人员健康状况严重恶化或需要外科干预，在此情形下，应归类 IIb 类。a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

用于监测生理过程的软件均归类 IIa 类，除非其专门用于监测重要生理参数，且这些参数变化的性质可导致患者面临紧急危险，在此情形下，应归类 IIb 类。 Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

所有其他软件均归类 I 类 All other software is classified as class I.

6.4. 规则 **12** Rule 12

所有向身体施用和/或从身体去除医疗产品、体液或其他物质的有源器械均归类 IIa 类，除非考虑到所涉及的物质性质、所涉及的身体任何部位以及应用方法，其执行方式具有潜在的风险，在此情形下，应归类 IIb 类。All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

6.5. 规则 **13** Rule 13

所有其他有源器械均归类 I 类。 All other active devices are classified as class I.

7. 特殊规则

7.1. 规则 **14** Rule 14

所有包括某种作为其构成整体所必需的部分的物质的器械，而这种物质根据第 2001/83/EC 号指令第 1 条第 2 点所规定，在单独使用时，可被视为一种医疗产品，包括该指令第 1 条第 10 点所定义的衍生自人体血液或血浆的医疗产品，且对该器械具有辅助作用，此类器械均归类为 III 类。 All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

7.2. 规则 **15** Rule 15

所有用于避孕或预防性病传播的器械均归类为 IIb 类，除非其为植入式或长期侵入性器械，在此情形下，应归类为 III 类。 All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

7.3. 规则 **16** Rule 16

所有专门用于隐形眼镜的消毒、清洗、漂洗、或水合（如适用）的器械均归类为于 IIb 类。 All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

所有用于医疗器械消毒或灭菌的器械均归类为于 IIa 类，除非其作为处理终点，是专门用于侵入性器械消毒的消毒溶液或清洗消毒器， 在此情形下， 应归类为 IIb 类。 All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

本规则并不适用于仅通过物理方法清洗， 除隐形眼镜以外器械， 的器械。 This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

7.4. 规则 **17** Rule 17

专门用于记录 X 射线辐射生成的诊断图像的器械均归类为 IIa 类。 Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

7.5. 规则 **18** Rule 18

所有利用非活性或处理为非活性的人体或动物源组织或细胞或其他衍生物制成的器械均归类为 III，除非此类器械仅用于直接接触无损皮肤。 All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

7.6. 规则 **19** Rule 19

所有纳入或包含纳米材料的器械应归类为： All devices incorporating or consisting of nanomaterial are classified as;

- 若其潜在内照射高或中等，则归类为 III 类； class III if they present a high or medium potential for internal exposure;
- 若其潜在内照射低，则归类为 IIb 类；class IIb if they present a low potential for internal exposure; and
- 若可忽略其潜在内照射，则归类为 IIa 类。 class IIa if they present a negligible potential for internal exposure.

7.7. 规则 **20** Rule 20

除外科侵入性器械外，所有预期通过吸入方式施用的，且与身体孔口相关的侵入性器械，属于 IIa 类，除非其作用方式对所施用的医疗产品的有效性和安全性具有显著影响以及那些预期用于治疗危及生命的情形的产品，在此情形下，应属于 IIb 类。 All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as class IIb.

7.8. 规则 **21** Rule 21

由某种物质或混合物组成并通过身体孔口被引入人体或施加到皮肤上且可由人体吸收或局部喷洒在人体上的器械应归类为： Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as:

- 若其或其代谢物由人体系统性地吸收以实现预期用途，则归类为 III 类； class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- 若其于胃或下消化道实现其预期用途或者其代谢物由人体系统性地吸收， 则归类为 III 类；class III if they

achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;

- 若其施用于皮肤或若其应用于鼻腔或咽部以上的口腔并于此类腔体内实现其预期用途，应归类为 IIa 类；class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
- 在其他所有情形下，均归类为 IIb 类。 class IIb in all other cases.

7.9. 规则 **22** Rule 22

具有集成或合并诊断功能，此功能是患者采用此器械治疗的主要因素，的有源治疗器械，如闭环系统或自动体外除颤器，应归类为 III 类。 Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

附录 IX

基于质量管理体系和技术文件评估的符合性评估

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

第 I 章：

质量管理体系 QUALITY MANAGEMENT SYSTEM

1. 如第 10(9)条所述，制造商应建立、记录和实施质量管理体系，并保持其在相关器械的整个生命周期内的有效性。制造商应确保质量管理体系的运行，如第 2 节规定，并根据第 2.3 和 2.4 节的规定进行审核，以及根据第 3 节的规定进行监管。 The manufacturer shall establish, document and implement a quality management system as described in Article 10(9) and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2 and shall be subject to audit, as laid down in Sections 2.3 and 2.4, and to surveillance as specified in Section 3.

2. 质量管理体系评估 Quality management system assessment

2.1. 制造商应向公告机构提出申请，评估自己的质量管理体系。申请应当包括： The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

- 制造商企业的名称和注册办公室地址以及质量管理体系覆盖的任何其他生产场所，若制造商申请由授权代表提出，同时也需要提供授权代表的姓名以及其注册营业地点的地址， the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business,
- 质量管理体系覆盖的器械或器械组的所有相关信息， all relevant information on the device or group of devices covered by the quality management system,
- 一份书面声明，表明没有向其他公告机构，就同一器械相关的质量管理体系提交申请，或给出同一器械相关的质量管理体系以往的信息， a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,
- 一份依据第 19 条和附录 IV 的欧盟符合性声明的草稿，针对符合性评估流程所覆盖的器械型号 a draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure
- 制造商质量管理体系的文件， the documentation on the manufacturer's quality management system,
- 一份相关程序的书面说明，其中包括履行质量管理体系中提出的义务及本法规所载的要求，以及相关制造商对使用这些程序的保证， a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures,
- 一份相关程序的说明，以确保保持质量管理体系的正确性和有效性，以及制造商对使用这些程序的保证， a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

- 制造商上市后监管体系和 PMCF 计划（如适用）的文档及适当的程序以保证其符合第 87 条至 92 条警戒规定的义务， the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,
- 一份相关程序的说明，以保持最新的上市后监管体系和 PMCF 计划（如适用），及适当的程序以保证其符合第 87 条至 92 条警示规定的义务， 以及制造商对使用这些程序的保证， a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,
- 临床评估计划的文件， documentation on the clinical evaluation plan, and
- 一份相关程序的说明， 以保持临床评估计划的更新， 并考虑目前工艺水平。 a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

2.2 质量管理体系的实施应确保遵守本法规的规定。制造商为其质量管理体系而采用的所有要素、要求和规定，必须以系统和有序的方式记录在质量手册、书面政策和程序之中，例如质量程序、质量计划和质量记录。

Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

此外，为质量管理体系的评估而提交的文件应包括适当的说明，特别是： Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) 制造商的质量目标； the manufacturer's quality objectives;

(b) 业务的组织，特别是： the organisation of the business and in particular:

- 对关键程序、管理人员的职责和其组织权力具有明确任务分配的组织结构， the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,
- 监管质量管理体系是否有效运行的方法， 特别是其实现预期的设计和器械质量的能力， 包括管理未符合要求的器械， the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,
- 器械的设计、制造和 /或最终验证和测试，或这些程序的任何部分，由另一方承担，质量管理体系有效运行的监管方法，特别是对其中一方施加的控制类型和程度， where the design, manufacture and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party, and
- 若制造商在某个成员国没有注册营业地址， 需提供一份授权草稿，任命一位授权代表，并且授权代表出具意向书，愿意接收这个授权； where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) 用于监控、验证、确认和控制器械设计的程序和技术，相应的文件以及这些程序和技术所产生的数据和记录，这些程序和技术应具体着眼于以下 the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover ：

- 法规符合性策略，包括确定相关法律要求、资质、分类、等效性处理、符合性评估流程的选取和遵守的过程， the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures,
- 确定适用的一般安全性与性能要求以及解决这些问题的方案，考虑采用适用的 CS 以及协调标准或其他适当的解决方案（如选择） ， identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS and, where opted for, harmonised standards or other adequate solutions into account,
- 附录 I 第 3 节所述的风险管理， risk management as referred to in Section 3 of Annex I,
- 临床评估， 根据第 61 条和附录 XIV 的规定， 包括上市后的临床跟踪， the clinical evaluation, pursuant to Article 61 and Annex XIV , including post-market clinical follow-up,
- 对于设计和构造，满足适用的具体要求，其解决方案包括适当的临床前评估，特别针对附录 I 第 II 章要求， solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,
- 对于和器械一同提供的信息，满足适用的具体要求的解决方案，特别针对附录 I 第 III 章要求，

solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,

- 草拟器械识别程序，在生产的每一个阶段，与图纸、规范或其他相关文件保持同步 the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and
- 设计的管理或质量管理体系的变更； management of design or quality management system changes; and

(d) 生产环节的验证和质量保证技术，特别是 the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents; and

- 将要使用的过程和流程，尤其是灭菌相关及相应文件，

(e) 制造前、制造中和制造后将要实施的适用的测试和试验，其发生的频率和使用的测试设备，并应能充分地追溯测试设备的校准情况。 the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

此外，制造商应给予公告机构权利， 获取附录 II 和 III 所述的技术文件。 In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. 审核 Audit

公告机构应审核质量管理体系，以确定它是否满足第 2.2 节中所述的要求。关于质量管理体系，若制造商使用了协调标准或 CS，公告机构应符合这些标准或 CS。对于满足相关协调标准或 CS 的质量管理体系，公告机构应假设其符合这些标准或 CS 涵盖的要求，除非有充分证据不可如是行事。 The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiates not doing so.

根据附录 VII 的第 4.3 节至第 4.5 节，公告机构的审核小组应至少包括一位具有相关技术评估经验的成员。 若这种经验不直观或不适用，公告机构应该提供包含该审团队的书面理由。评估流程应包括，基于制造商而做出的审核，如适用，应基于制造商的供应商和 /或分包商，以验证制造和其他相关过程。 The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

此外，若为 IIa 或 IIb 类器械，质量管理体系评估应伴随着器械技术文件的评估，按照第 4.4 至第 4.8 节的规定，器械的选择应具有代表性。 在选择代表性样本的过程中， 公告机构应考虑 MDCG 根据第 105 条而设计和发布的指南，特别是技术创新性，包括设计、技术、制造和灭菌方法、预期用途以及之前有关评估的结果（如就物理、化学、 生物或临床属性而言）执行。 相关公告机构应记录其样品选择的理由。 Moreover, in the case of class IIa and class IIb devices, the quality management system assessment shall be accompanied by the assessment of technical documentation for devices selected on a representative basis in accordance with Sections 4.4 to 4.8. In choosing representative samples, the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 105 and in particular the novelty of the technology, similarities in

design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

若质量管理体系符合本法规的有关规定，公告机构将出具的欧盟质量管理体系证书。公告机构应通知制造商其颁发证书的决议。该决议应包括审核结论和理由报告。 If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. 相关制造商应通知公告机构 （批准制造商的质量管理体系） ，其质量管理体系的任何重大变化计划， 或涵盖的器械范围的变化。公告机构应评估拟定修改，确定是否需要额外审核，并核实这些更改后的质量管理体系是否仍符合第 2.2 节所述的要求。此外，应将包括评估结论的决议通知制造商，或在适用情况下，包括额外审核结论。

对于质量管理体系或器械覆盖范围的重大改变，其批准过程应采取欧盟质量管理体系证书的补充形式。 The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. 适用于 **IIa**、**IIb** 和 **III** 类器械的监管评估 Surveillance assessment applicable to class IIa, class IIb and class III devices

3.1. 监管目的是确保制造商充分履行批准后的质量管理体系所规定的义务。 The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. 制造商应授权公告机构进行所有必要的审核， 包括现场审核， 并提供所有相关信息， 特别是： The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

- 质量管理体系的文件； the documentation on its quality management system,
- 使用上市后监管计划而获取的任何调查结果和结论，包括器械代表性样品，进行 PMCF 计划，以及第 87 至第 92 条所述的警戒规定， documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 87 to 92,
- 与设计相关的质量管理体系部分所规定的数据， 例如分析、 计算、 试验的结果以及针对附录 I 第 4 节所述风险管理所采用的解决方案， the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I, and
- 与制造相关的质量管理体系部分所规定的数据，例如，质量管理报告和试验数据、校准数据、相关人员的资质记录等。 the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. 公告机构应定期， 至少每隔 12 月开展一次适当的审核和评估，以确保相关制造商采用批准的质量管理体系和上市后监管计划。该审核和评估应包括对制造商经营场所的审核，必要时，还包括对制造商的供应商和 /或分包商

经营场所的审核。在进行现场审核时，若必要，公告机构应进行或要求进行试验，以便检查质量管理体系是否恰当发挥了作用。并应为制造商提供监管审核报告。若已进行试验，则其应为制造商提供试验报告。 Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. 公告机构至少应每隔五年随机对制造商进行一次现场突击审核，必要时，还应对制造商的供应商和/或分包商进行此类审核，并可结合第 3.3 节所述的定期监管评估或进行该监管评估以外的评估。公告机构应制定此类现场突击审核的计划，但不得向制造商披露。 The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3. or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

在进行此类现场突击审核时，公告机构应选取适当的生产器械或制造工艺的适当样品进行试验，以验证所制造的器械是否符合技术文件的要求，但第 52(8)条第二段所述器械除外。在进行现场突击审核前，公告机构应规定相关取样标准和检验程序。 Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

除了第二段所述的取样以外，公告机构还应进行器械的市场取样，以验证所制造的器械是否符合技术文件的要求，但第 52(8)条第二段所述的器械除外。在取样前，相关公告机构应规定相关取样标准和检验程序。 nstead of, or in addition to, sampling referred to in the second paragraph, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation, with the exception of the devices referred to in the second subparagraph of Article 52(8). Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

公告机构应为相关制造商提供现场审核报告，如适用，其中还应包括样品试验的结果。 The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. Iia 和 IIb 类器械的监管评估还应包括第 4.4 至 4.8 节所述的相关器械技术文件的评估。评估需基于更具代表性的样品选取。而这些样品的选择依据是公告机构根据第 2.3 节第二段所述之基本原理。 In the case of class IIa and class IIb devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 for the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the second paragraph of Section 2.3.

若为 III 类器械，则监管评估亦应包括对于器械完整性至关重要的批准零件和/或材料的测试，包括，如适用，应检验生产或采购的零件和/或材料数量以及相应的成品器械数量之间的一致性。 In the case of class III devices, the surveillance assessment shall also include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.

3.6. 公告机构应确保审核小组的成员是否具备充分的器械、系统以及相关工艺的评估经验，且其评估具有持续的客

观性和中立性，这应包括评估小组成员以适当的时间间隔轮流进行评估。一般而言，审核组组长连续领导和参与审核同一制造商的时间不得超过三年。 The notified body shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. 若公告机构发现生产器械或市场样品与技术文件或批准设计所规定的规格之间存在差异，则将吊销或撤销相关证书或对其施加限制。 If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

第 **II** 章：

技术文件评估 ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. 适用于第 **52**（**4**）条第二子段所述的 **III** 类和 **IIb** 类器械的技术文件评估

Assessment of the technical documentation applicable to class III devices and to the class IIb devices referred to in the second subparagraph of Article 52(4)

4.1. 除第 2 节所规定的义务以外，制造商还应向公告机构申请进行相关器械技术文件评估。这些器械包括制造商计划出售或交付使用的器械以及第 2 节所述质量管理体系所涵盖的器械。 In addition to the obligations laid down in Section 2, the manufacturer shall lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. 申请书应说明相关器械的设计、制造和性能。其应包括附录 II 和 III 中所述的技术文件。 The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

4.3. 公告机构应针对相关技术和临床应用方面的公认知识和经验来审查职员聘任申请。公告机构可要求提供根据进一步实施的试验或请求其他证据所填写的申请书，以使评估符合本法规的相关要求。公告机构应进行与器械相关的充分的物理或实验室试验， 或要求制造商进行此类试验。 The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of the Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. 公告机构应对制造商在临床评估报告中提交的临床证据，及相关临床评价报告进行审查。就该审查而言，公告机构应聘任临床专业知识丰富的器械审查员以及在相关器械临床应用方面或对器械所应用的临床病症方面具有直接和现有经验的外部临床专家 The notified body shall review the clinical evidence presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilised, for the purposes of that review.

4.5. 公告机构应部分或全部基于与评估器械等同器械的临床证据评估此类数据的适用性，同时还应考虑到新适应症和创新性等因素。公告机构应明确记录其对于所公布数据等效性、相关性和充分性的结论，以证明数据符合要求。对于制造商宣称的器械创新特征或新适应症，公告机构应通过特定的临床前和临床中数据及风险分析进行

评估。 The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.

4.6. 公告机构应验证临床证据和临床评价是否充分，并验证制造商所得出的结论是否符合一般安全性与性能要求。该验证应包括考虑分析与收益风险评定充分性、 风险管理、 使用说明书、 使用者培训以及制造商的 PMCF 计划，如适用，还应包括审查拟定上市后临床跟踪的必要性和充分性。 The notified body shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.

4.7. 根据其对产品临床证据、临床评估、及风险与收益的综合评估，公告机构应考虑是否需要确定特定节点，以便公告机构根据上市后监管和 PMCF 数据对更新的临床证据进行审查。 Based on its assessment of the clinical evidence, the notified body shall consider the clinical evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMCF data.

4.8. 公告机构应在临床评估的评定报告中明确记录其评价结果。 The notified body shall clearly document the outcome of its assessment in the clinical evaluation assessment report.

4.9. 欧盟公告机构应向制造商提供技术文件评估报告，包括临床评估的评定报告。若器械符合本法规相关规定，则公告机构应颁发 EU 技术文件评估证书。证书中应包括技术文件评估结论、证书有效性条件、确定合格设计所需资料及， 如适用， 对器械预期目的说明。 The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved design, and, where appropriate, a description of the intended purpose of the device.

4.10 若已批准器械发生会影响器械安全与性能的变更或器械的使用条件发生变更，则这些变更应需要获得颁发 EU 技术文件评估证书的公告机构的批准。若制造商计划进行任何上述变更，则其应通知本文件所述颁发 EU 技术文件评估证书的公告机构。 公告机构应评估申请变更并确定是否需要根据第 52 条对申请变更重新进行符合性评估，或是否可通过 EU 技术文件评估证书的附件的形式予以说明。对于后者情况，公告机构应评估变更，并将其决议告知制造商，且若这些变更获得批准，则公告机构还应为制造商提供 EU 技术文件评估证书的附件。 Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5. 特殊程序 Specific additional procedures

5.1. 特定 III 类和 IIb 类有源植入式器械的评估过程

Assessment procedure for certain class III and class IIb devices

(a) 对于 III 类可植入装置，以及用于如在附录 VIII 第 6.4 节中（规则 12）所述的用于施用和/或去除药品的 IIb 类有源装置。公告机构应参考第 61（12）制造商提供的临床评价核实临床数据质量，并编制临床评估的评定报告，特别针对收益风险判断及与预期用途证据的一致性，包括医学指征，以及第 10（3）条和附录 XIV 第 B 部分中所述 PMCF 计划，生成临床评估的评定报告，就制造商提供的临床证据得出结论。 For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12), the notified body shall, having verified the quality of clinical data supporting the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a clinical evaluation assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan referred to in Article 10(3) and Part B of Annex XIV.

公告机构应将其临床评估的评定报告，与附录 II 第 6.1（c）和（d）点所述制造商的临床评价文档一起提交给欧盟委员会。 he notified body shall transmit its clinical evaluation assessment report, along with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1 of Annex II, to the Commission.

欧盟委员会应立即将这些文档发送至第 106 条所述的有关专家小组。 The Commission shall immediately transmit those documents to the relevant expert panel referred to in Article 106.

(b) 公告机构可能被要求向相关专家小组出示 (a)点所述的评估结论。 The notified body may be requested to present its conclusions as referred to in point (a) to the expert panel concerned.

(c) 专家小组基于以下全部标准，在欧盟委员会的监督下做出决议： The expert panel shall decide, under the supervision of the Commission, on the basis of all of the following criteria:

(i) 器械的创新性或可能涉及和主要临床影响或健康影响的相关临床操作； the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof;

(ii) 从特定品类器械或器械组收益风险比上观察产生的显著有害变化，是由有关组件或原材料，或有关器械故障的情况下对健康有影响的，科学有效的健康隐患所引起； a significantly adverse change in the benefit-risk profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in the case of failure of the device;

(iii) 根据第 87 条，与特殊品类器械或器械组有关的严重不良事件报告的显著增加。 a significantly increased rate of serious incidents reported in accordance with Article 87 in respect of a specific category or group of devices,

若根据制造商提供的临床证据，针对公告机构的临床评估的评定报告发表科学意见，特别是关于收益/风险判断，及与医疗指征证据和 PMCF 计划的一致性。该科学意见应，自委员会提供 (a)点所述的文件 60 天内给出。决议根据（i）、（ii）和（iii）点中所列标准提供科学意见的原因也应包括在科学意见内。若所提交的信息不够充分，专家小组无法得出结论，应在科学意见中予以说明。 whether to provide a scientific opinion on the clinical evaluation assessment report of the notified body based on the clinical

evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the medical indication or indications and the PMCF plan. That scientific opinion shall be provided within a period of 60 days, starting on the day of receipt of the documents from the Commission as referred to in point (a). The reasons for the decision to provide a scientific opinion on the basis of the criteria in points (i), (ii) and (iii) shall be included in the scientific opinion. Where the information submitted is not sufficient for the expert panel to reach a conclusion, this shall be stated in the scientific opinion.

(d） 专家小组可基于（ c）点规定的标准，在欧盟委员会的监督下，决议不提供科学的意见，这种情况应在收到委员会 (a)点所述的文档后 21 天内尽快通知公告机构。专家小组应在期限内向公告机构和欧盟委员会说明该决议原因，使公告机构可继续该器械的认证程序。 The expert panel may decide, under the supervision of the Commission, on the basis of the criteria laid down in point (c) not to provide a scientific opinion, in which case it shall inform the notified body as soon as possible and in any event within 21 days of receipt of the documents as referred to in point (a) from the Commission. The expert panel shall within that time limit provide the notified body and the Commission with the reasons for its decision, whereupon the notified body may proceed with the certification procedure of that device.

(e） 专家小组应在收到欧盟委员会文档后 21 天内，通过欧盟医疗器械数据库确定是否根据（ c）点提供科学意见， 或根据（ca）点不提供科学意见。 The expert panel shall within 21 days of receipt of the documents from the Commission notify the Commission, through Eudamed whether it intends to provide a scientific opinion, pursuant to point (c), or whether it intends not to provide a scientific opinion, pursuant to point (d).

(f） 如未在 60 天内提出意见， 则公告机构可继续相关器械的认证程序。 Where no opinion has been delivered within a period of 60 days, the notified body may proceed with the certification procedure of the device in question.

(g) 公告机构应适当考虑专家小组的科学意见中表达的观点。若专家小组发现临床证据不足以判断收益 / 风险、是否与预期用途证据的一致性，包括医学适应症和 PMCF 计划，或所产生的相关严重问题，必要时，公告机构应建议制造商限制器械用于特定患者或特定医学指征，和 /或限制证书的有效期，进行特定 PMCF 研究以适应使用说明或安全性和临床总结，或限制其一致性评估报告（如适用） 。在公告机构未遵照其一致性评估报告时，应提供充分理由，且欧盟委员会应在不影响第 109 条的情况下，通过欧盟医疗器械数据库公开专家小组的科学意见和公告机构的书面理由。 The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. Where the expert panel finds that the level of clinical evidence is not sufficient or otherwise gives rise to serious concerns about the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s), and with the PMCF plan, the notified body shall, if necessary, advise the manufacturer to restrict the intended purpose of the device to certain groups of patients or certain medical indications and/or to impose a limit on the duration of validity of the certificate, to undertake specific PMCF studies, to adapt the instructions for use or the summary of safety and performance, or to impose other restrictions in its conformity assessment report, as appropriate. The notified body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report and the Commission shall without prejudice to Article 109 make both the scientific opinion of the expert panel and the written justification provided by the notified body publicly available via Eudamed.

(h） 欧盟委员会与成员国及相关专家咨询后，应在 2020 年 5 月 26 日前向专家小组提供指导，并基于（ c）点标准达成一致。 The Commission, after consultation with the Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the criteria in point (c) before 26 May

2020.

5.2. 与药物一同使用的器械的认证程序

Procedure in the case of devices incorporating a medicinal substance

(a) 如器械结合根据第 2001/83/EC 号指令第 1 条第 2 点内容可视为药品的物质一同使用时，包括人血或人血浆源医疗产品，须根据第 2001/83/EC 号指令附录 I 中指定的方法对该物质的质量、安全性和有效性进行验证。 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma and that has an action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.

(b) 颁发欧盟技术文件评估证书前，公告机构应核实该物质作为器械一部分的有用性，考虑到器械的预期用途，寻求成员国根据第 2001/83/EC 号指令指定的主管机构或 EMA 提供的科学意见，特别本节根据此点咨询的“药品产品权威咨询”，包括器械结合物质使用的收益/风险。结合人血或人血浆衍生物使用时，如器械被视为欧洲委员会第 726/2004 号法规附录范围内的医疗产品，则公告机构应咨询 EMA 意见。Before issuing an EU technical documentation assessment certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as ‘the medicinal products authority consulted’ depending on which has been consulted under this point, on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device. Where the device incorporates a human blood or plasma derivative or a substance that, if used separately, may be considered to be a medicinal product falling exclusively within the scope of the Annex to Regulation (EC) No 726/2004, the notified body shall seek the opinion of the EMA.

(c) 发布意见时，医疗产品咨询主管机构应考虑到公告机构确定的器械中所采用材料的可用性相关的制造工艺和数据。 When issuing its opinion, the medicinal products authority consulted shall take into account the manufacturing process and the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body.

(d) 医疗产品咨询主管机构应在收到所有必要文档 210 天内向公告机构提供意见。 The medicinal products authority consulted shall provide its opinion to the notified body within 210 days of receipt of all the necessary documentation.

(e) 医疗产品咨询主管机构的科学意见及可能的更新应包含在公告机构有关该器械的文档中。公告机构做出决议时，应适当考虑其科学意见所表达观点。如其科学意见表示反对，则公告机构不可颁发证明，且应向医药产品咨询当传达最终决议。 The scientific opinion of the medicinal products authority consulted, and any possible update of that opinion, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable and shall convey its final decision to the medicinal products authority consulted.

(f) 器械中结合的辅助物质发生改变之前，特别是其制造过程发生改变前，制造商应通知公告机构相应的变更。公告机构应寻求医疗产品咨询主管机构意见已确保该辅助物质的质量和安全性保持不变。医疗产品

咨询主管机构应考虑有关公告机构确定该物质纳入器械的可用性数据，以便确保这些变更不会对先前建立的器械中添加物质相关临床收益或风险产生负面影响。医疗产品咨询主管机构应在收到有关变更的所有必要文档后 60 天内提出意见。如医疗产品咨询主管机构的科学意见表示反对，则公告机构不可提出 EU 技术文件评估报告之增补。公告机构应向相关主管机构传达最终决议。 Before any change is made with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the manufacturer shall inform the notified body of the changes. That notified body shall seek the opinion of the medicinal products authority consulted, in order to confirm that the quality and safety of the ancillary substance remain unchanged. The medicinal products authority consulted shall take into account the data relating to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The medicinal products authority consulted shall provide its opinion within 60 days after receipt of all the necessary documentation regarding the changes. The notified body shall not deliver the supplement to the EU technical documentation assessment certificate if the scientific opinion provided by the medicinal products authority consulted is unfavourable. The notified body shall convey its final decision to the medicinal products authority consulted.

(g) 若医疗产品咨询主管机构获得有关辅助物质的以下信息：该物质可能会对先前建立的器械中添加该物质相关临床收益或风险产生影响，应提供建议给公告机构，该信息是否影响已建立的器械中添加物质相关临床收益或风险。在重新审核的法规符合性评估流程中，公告机构应考虑该建议。 Where the medicinal products authority consulted obtains information on the ancillary substance, which could have an impact on the risk or benefit previously established concerning the incorporation of the substance into the device, it shall advise the notified body as to whether this information has an impact on the risk or benefit previously established concerning the incorporation of the substance into the device. The notified body shall take that advice into account in reconsidering its assessment of the conformity assessment procedure.

5.2. 利用非活性或处理为非活性的人类或动物源组织或细胞及其衍生物制造器械时的认证程序

Procedure in the case of devices manufactured utilising, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

5.3.1 人类源组织或细胞及其衍生物 Tissues or cells of human origin or their derivatives

(a) 根据本法规第 1(6)节（ g）点，利用人类组织或细胞衍生物制造器械，或结合第 2004/23/EC 号指令，使用组织或人类细胞及其衍生物的器械，公告机构应在颁发欧盟技术文件评估证书之前，应向成员国第 2004/23/EC 号指令指定的主管机构之一（ “人类组织和细胞主管机构” ）寻求有关人类组织或细胞或其衍生物的捐赠、采购和检测方面的科学意见。公告机构应提交初步符合性评估总结，说明及相应捐赠、采购和检测的人类组织或细胞无存活能力， ，以及结合人类源组织或细胞及其衍生物使用的器械的风险或收益等相关信息： For devices manufactured utilising derivatives of tissues or cells of human origin that are covered by this Regulation in accordance with point (g) of Article 1(6) and for devices that incorporate, as an integral part, tissues or cells of human origin, or their derivatives, covered by Directive 2004/23/EC, that have an action ancillary to that of the device, the notified body shall, prior to issuing an EU technical documentation assessment certificate, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2004/23/EC (‘ human tissues and cells competent authority ’) on the aspects relating to the donation, procurement

and testing of tissues or cells of human origin or their derivatives. The notified body shall submit a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the human tissues or cells in question, their donation, procurement and testing and the risk or benefit of the incorporation of the tissues or cells of human origin or their derivatives into the device.

(b) 在收到所有必要文档后 120 天内，人类组织和细胞主管机构应向公告机构提供意见。 Within 120 days of receipt of all the necessary documentation, the human tissues and cells competent authority shall provide to the notified body its opinion.

(c) 人类组织和细胞主管机构的科学意见及可能更新都应包含在公告机构有关器械的文档中。公告机构做出决议时，应适当考虑人类组织和细胞主管机构的科学意见所表达的观点。如科学意见表示反对，则公告机构不可颁发证书。 应向相关人类组织和细胞主管机构传达最终决议。 The scientific opinion of the human tissues and cells competent authority, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion of the human tissues and cells competent authority when making its decision. The notified body shall not deliver the certificate if that scientific opinion is unfavourable. It shall convey its final decision to the human tissues and cells competent authority concerned.

(d) 在器械中结合的非活性人类源组织或细胞及其衍生物发生变更之前，特别是其捐赠、检验或采购过程发生变更前，制造商应通知公告机构相应变更。公告机构应咨询主管机构有关初次咨询的内容，以确保人类组织或细胞或其衍生物的质量和安全性。相关人类组织和细胞主管机构应考虑由公告机构所确定的与人类组织或细胞及其衍生物一同使用器械的可用性数据，以确保该项变更对器械中增加人类组织或细胞及其衍生物已确定的收益 /风险比无负面影响。 应在收到有关预期变更的所有比伊奥文档后 60 天内提出意见。若科学意见表示反对， 则公告机构不可颁发 EU 技术文件评估报告的增补件， 并应向相关人类组织和细胞主管机构传达最终决议。 Before any change is made with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement, the manufacturer shall inform the notified body of the intended changes. The notified body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained. The human tissues and cells competent authority concerned shall take into account the data relating to the usefulness of incorporation of the tissues or cells of human origin or their derivatives into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit-risk ratio of the addition of the tissues or cells of human origin or their derivatives in the device. It shall provide its opinion within 60 days of receipt of all the necessary documentation regarding the intended changes. The notified body shall not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and shall convey its final decision to the human tissues and cells competent authority concerned.

5.3.2 动物源组织或细胞及其衍生物 Tissues or cells of animal origin or their derivatives

根据第 722/2012 号法对于利用源自动物组织的非活性或处理为非活性医疗产品利用动物组织制造的器械， 公告机构应采用该法规规定的相关要求。 In the case of devices manufactured utilising animal tissue which is rendered non-viable or utilising non-viable products derived from animal tissue, as referred to in Regulation (EU) No 722/2012, the notified body shall apply the relevant requirements laid down in that Regulation

5.3. 对于包含可被人体吸收或局部喷洒在人体上的物质或物质组合的器械

5.4. Procedure in the case of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

(a) 器械包含可通过身体孔口进入人体，或涂敷在皮肤上被人体吸收，或局部喷洒在人体上的物质或物质组合时，应根据第 2001/83/EC 号指令附录 I 中关于器械吸收、分布、代谢、排泄、局部耐受性、毒性、与其他器械或医疗产品或其他物质相互作用及潜在不良反应的相关要求，验证该器械的质量和安全性是否适用于本法规，且不限于本法规的要求。 The quality and safety of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by, or locally dispersed in, the human body, shall be verified where applicable and only in respect of the requirements not covered by this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions.

(b) 同时，器械或其代谢产物可被人体吸收以实现预期用途时，公告机构应当就器械与第 2001/83/EC 号指令 EMA 寻求科学意见，其中根据此点上咨询内容，任一个在本节中称为“咨询的药品产品权威”，且该器械是否符合指令 2001/83/EC 附件 I 中规定的相关要求 In addition, for devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, the notified body shall seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as ‘the medicinal products authority consulted’ depending on which has been consulted point, on the compliance of the device with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

(c) 医疗产品咨询主管机构应在收到所有必要文档后 150 天内提出意见。 The opinion of the medicinal products authority consulted shall be drawn up within 150 days of receipt of all the necessary documentation.

(d) 医疗产品咨询主管机构的科学意见及可能更新应包含在公告机构有关该器械的文档中。公告机构做出决议时，应适当考虑科学意见所表达观点，并应向医疗产品咨询主管机构传达最终决议。 The scientific opinion of the medicinal products authority consulted, and any possible update, shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision and shall convey its final decision to the medicinal products authority consulted.

6. 在器械包括药用物质作为组成部分的情况下的批量验证，若单独使用，可认为其是第 1（8）条所述的人血或人血浆医疗产品。 Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in Article 1(8)

当结合人血或血浆源医疗产品使用时，根据第 1(8)条第 1 段，器械制造完成后，制造商应告知公告机构器械批号，并向公告机构发送成员国国家实验室或根据第 2001/83/EC 号指令第 114(2)节由成员国指定实验室所颁发的使用人血或血浆衍生物器械的官方证明。 Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

第 **III** 章：

行政管理规定 **ADMINISTRATIVE PROVISIONS**

7. 制造商或其授权代表（如制造商在成员国内未登记营业场所）应在最后一个器械投放市场至少 10 年内（植入式器械为至少 15 年内），按照主管机构指示，保管以下文件： The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- EU 符合性声明； the EU declaration of conformity,
- 第 2.1 节第五段所述的文件，尤其是第 2.2 节第二段（ c）点所述程序所产生的数据和记录， the documentation referred to in the fifth indent of Section 2.1 and in particular the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2,
- 第 2.4 节所述变更， information on the changes referred to in Section 2.4,
- 第 4.2 节所述文档，以及 the documentation referred to in Section 4.2, and
- 如本附录所述公告机构的决议和报告。 the decisions and reports from the notified body as referred to in this Annex.

8. 各成员国应要求，若制造商或其在职权范围内所确定的授权代表在前段第一句所示期限到期前破产或停止其业务活动，则第 7 节所述文件在上述所述期间由主管机构保管。 Each Member State shall require that the documentation referred to in Section 7 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

附录 X
基于型式检验的符合性评估 CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

1. 欧盟型式试验指的是欧盟公告机构确认器械性能并颁发合格证书的过程，包括其技术文件及相应符合本法规相关规定的器械代表性产品样品。 EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions of this Regulation.

2. 申请表 Application

制造商应向认证机构提交评估申请。 申请表应当包括： The manufacturer shall lodge an application for assessment with a notified body. The application shall include:

– 制造商名称和注册地址，如由授权代表进行申请表，还须提供授权代表名字及其注册营业地点的地址， the name of the manufacturer and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business,

– 附录 II 和 III 所述技术文件。申请人应提供相关代表性器械生产样品，适用于公告机构的“型式”（‘type’）。必要时，公告机构可要求申请人提供其他样品； the technical documentation referred to in Annexes II and III. The applicant shall make a representative sample of the device production envisaged (‘type’) available to the notified body. The notified body may request other samples as necessary, and

– 未向任何其他公告机构提出同一型式申请表的书面声明，或先前由另一公告机构驳回或在其他公告机构进行最终评估前制造商或其授权代表撤回的任何同一型式申请表的相关信息。 a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

3. 评估 Assessment

公告机构应： The notified body shall:

(a) 现场检查制造商的雇员是否具有相关技术及其临床应用知识与丰富经验。欧盟公告机构可要求提供进行的进一步测试或请求提供其他证据评估器械是否符合法规有关规定，从而完成申请表。公告机构应进行与器械相关的适当物理或实验室试验，或要求制造商进行此类试验。 examine the application by using staff with proven knowledge and experience regarding the technology concerned and its clinical application. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests;

(b) 审查和评估技术文件是否符合本法规中适用于器械的要求，并验证所生产的型式是否符合文件的要求；还应记录所设计的项目是否符合第 8 条或适用的 CS 所述标准的相关规范要求，以及记录未涉及的项目是否基于第 8 条或相关 CS 所述标准的相关规定； examine and assess the technical documentation for conformity with the requirements of this Regulation that are applicable to the device and verify that the type has been manufactured in conformity with that documentation; it shall also record the items designed in conformity with the applicable standards referred to in Article 8 or with applicable CS, and record the items not designed on the basis of the relevant standards referred to in Article 8 or of the relevant CS;

(c) 按照附录 XIV 第 4 节审查制造商提交的临床评价报告中的临床证据。欧盟公告机构应聘请具有足够临床经验的器械审查员以及在必要时使用具有相关器械或使用该器械的临床条件的直接和当前经验的外部临床专家； review the clinical evidence presented by the manufacturer in the clinical evaluation report in accordance with Section 4 of Annex XIV. The notified body shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or to the clinical condition in which it is utilised, for the purposes of that review;

(d) 若临床证据全部或部分基于所公布器械的数据，且这些器械与所评估的器械类似或相同，则公告机构应评估此类数据的适用性，并考虑新趋势和创新等因素。公告机构应明确记录其对于所公布数据等效性、相关性和充分性的结论，以证明数据符合要求。 in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity;

(e) 根据第（i）点在临床前和临床评价报告中清楚记录评估结果， 加入欧盟型式试验报告中。 clearly document the outcome of its assessment in a pre-clinical and clinical evaluation assessment report as part of the EU type examination report referred to in point (i);

(f) 进行或安排相应的评估以及必要的物理或实验室试验，以验证在未采用第 8 条或 CS 所述标准的情况下，制造商所采用的解决方案是否满足本法规的通用安全与性能要求；若器械运行需与其他器械相连接，则应证明在其与具有制造商所规定特性的任何此类器械相连接时， 其符合通用安全与性能要求； carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements laid down in this Regulation, in the event that the standards referred to in Article 8 or the CS have not been applied. Where the device has to be connected to another device or devices in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such device or devices having the characteristics specified by the manufacturer;

(g) 进行或安排相应的评估以及必要的物理或实验室试验，以验证制造商所选择采用的相关协调标准是否得到了实际采用； carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, in the event that the manufacturer has chosen to apply the relevant harmonised standards, those standards have actually been applied;

(h) 与申请人商定进行必要评估和试验的场所；以及 agree with the applicant on the place where the necessary assessments and tests are to be carried out; and

(i) 根据第 (a)至(g) 点进行评估和测试，基于相关结果编制欧盟型式试验报告。 draw up an EU type-examination report on the results of the assessments and tests carried out under points (a) to (g).

4. 证书 Certificate

若型式符合本法规的规定，则公告机构应颁发 EC 型式检验证书。证书应包含制造商的名称和地址、型式试验评估结论、证书有效性条件以及批准型式标识所需的数据。根据附录 XII 编制证明。文件的相关部分应附于证书之后，且公告机构应保存其副本。 If the type conforms to this Regulation, the notified body shall issue an EU type-examination certificate. The certificate shall contain the name and address of the manufacturer, the conclusions of the type examination assessment, the conditions of the certificate's validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XII. The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.

5. 型式变更 Changes to the type

5.1. 申请人应将批准型式或其预期用途和使用条件的任何计划变更通知给颁发 EC 型式检验证书的公告机构。 The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

5.2. 经认可器械的变化，包括预期用途限制和使用条件等，如影响与通用安全与性能要求的一致性或产品的特定使用条件， 则应需要经过欧盟公告机构的审批， 由欧盟公告机构颁发 EC 型式检验证书。 公告机构应审查计划的变更，将其决议告知制造商，并为其提供 EU 型式检验报告的附录。对批准型式任何变更的批准应作为 EC 型式检验证书的附录附于其后。 Changes to the approved device including limitations of its intended purpose and conditions of use shall require approval from the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product. The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the EU type-examination certificate.

5.3. 批准器械预期用途和使用条件（预期用途和使用条件的限制除外）的变更应必需重新申请表进行符合性评估。 Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, shall necessitate a new application for a conformity assessment.

6. 具体程序 Specific additional procedures

附录 IX 第 5 节应适用，但条件是应参考欧盟技术文件，且认定证书应理解为参考 EC 型式检验证书。 Section 5 of Annex IX shall apply with the proviso that any reference to an EU technical documentation assessment certificate shall be understood as a reference to an EU type-examination certificate.

7. 行政管理规定 Administrative provisions

制造商或其授权代表 （如制造商在成员国内未登记营业地） 应在最后一个器械上市至少 10 年内（植入式器械为至少 15 年内），按照主管机构指示，保管以下文件： The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- 第 2 节第二段所述的文件， the documentation referred to in the second indent of Section 2,
- 如第 5 节所述的变更信息。 information on the changes referred to in Section 5, and
- EC 型式检验证书副本、科学意见与报告及其附录 /附录。 copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

附 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

附录 **XI**

基于产品合规性验证的符合性评估

CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION

1. 基于产品合规性验证的符合性评估的目的是确保器械符合已发布 EC 型式检验证书中所说明的形式，并满足本法规中的适用规定要求。 The objective of the conformity assessment based on product conformity verification is to ensure that devices conform to the type for which an EU type-examination certificate has been issued, and that they meet the provisions of this Regulation which apply to them.

2. 如已根据附录 X 颁发 EC 型式检验证书，制造商可申请表第 A 部分所述流程（生产质量保证），或本附录第 B 部分所述流程（产品验证）。 Where an EU type-examination certificate has been issued in accordance with Annex X, the manufacturer may either apply the procedure set out in Part A (production quality assurance) or the procedure set out in Part B (product verification) of this Annex.

3. 通过豁免上述第 1 节和第 2 节，本附录所述程序加上附录 II 和 III 所述技术文件也可适用于 IIa 类器械制造商。 By way of derogation from Sections 1 and 2 above, the procedures in this Annex coupled with the drawing up of technical documentation as set out in Annexes II and III may also be applied by manufacturers of class IIa devices.

第 **A** 部分： PART A

生产质量保证 PRODUCTION QUALITY ASSURANCE

4. 制造商应确保实施批准的相关器械生产质量管理体系，并按照第 6 节的规定进行最终验证，且接受第 7 节所述的监管。 The manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out a final verification, as specified in Section 6, and shall be subject to the surveillance referred to in Section 7.

5. 制造商应履行第 4 节所规定的义务， 并根据第 19 条和附录 IV 起草并保存符合性评估流程所涵盖器械型号的 EU 符合性声明。 通过发布 EC 符合性声明， 制造商应确定并声明有关器械是否符合 EC 型式检验证书中所说明的型式，以及是否满足本法规中的适用规定要求。 When the manufacturer fulfils the obligations laid down in Section 4, it shall draw up and keep an EU declaration of conformity in accordance with Article 19 and Annex IV for the device covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer shall be deemed to ensure and to declare that the device concerned conforms to the type described in the EU type-examination certificate and meets the requirements of this Regulation which apply to the device.

6. 质量管理体系 Quality management system

6.1 制造商应向公告机构提出申请表，评估自己的质量管理体系。申请表应当包括： The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

- 附录 IX 第 2.1 节所列的所有要素； all elements listed in Section 2.1 of Annex IX,
- 附录 II 和 III 所述批准型式的技术文件； the technical documentation referred to in Annexes II and III for the types approved, and

- 附录 X 第 4 节所述 EC 型式检验证书副本；若提出申请表后，EC 型式检验证书由同一公告机构颁发，则技术文件及其更新信息和所颁发证书的参考资料应包含在申请中。 a copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

6.2 质量管理体系的实施应确保器械是否符合 EC 型式检验证书中所说明的型式，以及是否满足本法规中的适用于各阶段器械的规定要求。制造商为其质量管理体系而采用的所有要素、要求和规定，必须以系统和有序的方式记录在质量手册、书面政策和程序之中，例如质量程序、质量计划和质量记录。 Implementation of the quality management system shall be such as to ensure that there is compliance with the type described in the EU type-examination certificate and with the provisions of this Regulation which apply to the devices at each stage. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

该文件尤其应包括对附录 IX 第 2.2 节（a）、（b）、（d）和（e）所列所有要素的适当说明。 That documentation shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 2.2 of Annex IX.

6.3 附录 IX 第 2.3 节第一和第二段的规定适用。 The first and second paragraph of Section 2.3 of Annex IX shall apply.

若质量管理体系可确保器械符合 EC 型式检验证书中所说明的形式，并满足本法规中的适用规定要求，则欧盟公告机构应出具欧盟质量保证证书。公告机构应将该决议通知制造商。该决议应包含公告机构审核和合理评估的结论。 If the quality management system is such that it ensures that the devices conform to the type described in the EU type-examination certificate and that it conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The notified body shall notify the manufacturer of its decision to issue the certificate. That decision shall contain the conclusions of the notified body's audit and a reasoned assessment.

6.4 附录 IX 第 2.4 节规定应适用。 Section 2.4 of Annex IX shall apply.

7. 监测 Surveillance

附录 IX 第 3.1 节、第 3.2 节第一段、第二段和第四段、第 3.3 节、第 3.4 节、第 3.6 节和第 4.7 节的规定适用。

对于 III 类器械，监管还应包括检查生产或购买原材料或批准用于该类型的关键部件的数量，且应与成品器械数量相对应。 Section 3.1, the first, second and fourth indents of Section 3.2, Sections 3.3, 3.4, 3.6 and 3.7 of Annex IX shall apply.

In the case of class III devices, surveillance shall also include a check that the quantities of produced or purchased raw material or crucial components approved for the type and correspond to the quantities of finished devices.

8 结合药物共同使用时，根据第 1(8)条器械可被视为整体部分的人血样或血浆源医药产品按批次进行验证

结合药物共同使用，根据第 1(8) 条第一子段可被视为整体部分的人血样或血浆源医药产品的器械生产完成后，制造商应通知欧盟公告机构器械批号，并向欧盟公告机构发送成员国国家实验室或根据第 2001/83/EC 号指令第 114(2) 节由成员国指定实验室颁发的使用人血液或血浆衍生物器械的官方证明。 Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance

which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC

9. 行政管理规定 Administrative provisions

制造商或其授权代表 （如制造商在成员国内无注册地址） 应在最后一个器械上市至少 10 年内（植入式器械为至少 15 年内）按照主管机构指示，保管以下文件： The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- EU 符合性声明； the EU declaration of conformity,
- 附录 IX 第 2.1 节第五段所述的文件， the documentation referred to in the fifth indent of Section 2.1 of Annex IX,
- 附录 IX 第 2.1 节第八段所述的文件， 包括附录 X 所述的 EC 型式检验证书， the documentation referred to in the eighth indent of Section 2.1 of Annex IX, including the EU type-examination certificate referred to in Annex X,
- 附录 IX 第 2.4 节所述的变更信息； 以及 information on the changes referred to in Section 2.4 of Annex IX, and
- 附录 IX 第 2.3、3.3 和 3.4 节所述的公告机构决议和报告。 the decisions and reports from the notified body as referred to in Sections 2.3, 3.3 and 3.4 of Annex IX.

附录 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

10 适用于 IIa 类器械 Application to class IIa devices

10.1 通过豁免第 5 节，制造商可根据 EC 符合性，确定并声明相关 IIa 类器械是否符合附录 II 和 III 所述技术文件，以及是否满足本法规中的适用规定要求。 By way of derogation from Section 5, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

10.2 对于 IIa 类器械，作为第 6.3 节所述评估的一部分，欧盟公告机构应评估附录 II 和 III 所述技术文件中所选器械是否符合本法规规定。 For class IIa devices the notified body shall assess, as part of the assessment referred to in Section 6.3, whether the technical documentation as referred to in Annexes II and III for the devices selected on a representative basis is compliant with this Regulation.

在选择器械的代表性样品时，欧盟公告机构应考虑到技术的创新性，设计、工艺、生产和灭菌方法的相似性，预期用途和之前根据本法规进行的有关评估结果（如物理、化学、生物或临床特性） 。欧盟公告机构应记录其选

择器械样品的理由。 In choosing a representative sample or samples of devices, the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of any previous relevant assessments (e.g. with regard to physical, chemical, biological or clinical properties) that have been carried out in accordance with this Regulation. The notified body shall document its rationale for the sample or samples of devices taken.

10.3 如按照第 10.2 节进行评估， 结果确认 IIa 类器械符合附录 II 和 III 所述技术文件， 并满足本法规本部分中的适用规定要求，欧盟公告机构应根据本附录该节出具证明。 Where the assessment under Section 10.2. confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

10.4 作为第 7 节所述监管评估的一部分，欧盟公告机构应对器械进行再次抽样评估。 Samples additional to those taken for the initial conformity assessment of devices shall be assessed by the notified body as part of the surveillance assessment referred to in Section 7.

10.5 通过豁免第 6 节，制造商或其授权代表应在最后一个器械上市至少 10 年内，按照主管机构指示， 保管以下文件： By way of derogation from Section 6, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- EC 符合性声明； the EU declaration of conformity,
- 附录 II 和 III 所述技术文件， the technical documentation referred to in Annexes II and III, and
- 第 10.3 节所述证书。 the certificate referred to in Section 10.3.

附录 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

第 **B** 部分： PART B

产品验证 PRODUCT VERIFICATION

11 产品验证应理解为指产品经制造商检查后，根据第 19 条和附录 IV 出具 EC 符合性声明，并依据第 14 节和第 15 节所述过程确定并声明并器械是否符合 EC 型式检验证书中所说明的形式， 并满足本法规中适用规定要求的过程。 Product verification shall be understood to be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing an EU declaration of conformity in accordance with Article 19 and Annex IV, shall be deemed to ensure and to declare that the devices which have been subject to the procedure set out in Sections 14 and 15 conform to the type described in the EU type-examination certificate and meet the requirements of this Regulation which apply to them.

12 制造商应采取一切必要措施，以确保生产的器械均符合 EC 型式检验证书中所说明的形式，并满足本法规中适用规定的要求。生产开始前，制造商应规定文档定义生产流程，特别是与必要消毒和所有预先确定的日常规定有关的流程，以保证生产同类产品，并符合 EC 型式检验证书中所说明的形式，且满足本法规中适用规定的要求（如适用）。The manufacturer shall take all the measures necessary to ensure that the manufacturing

process produces devices which conform to the type described in the EU type-examination certificate and to the requirements of the Regulation which apply to them. Prior to the start of manufacture, the manufacturer shall prepare documents defining the manufacturing process, in particular as regards sterilisation where necessary, together with all routine, pre-established procedures to be implemented to ensure homogeneous production and, where appropriate, conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

此外，对于上市的无菌器械以及用于确保和维护无菌条件的生产过程，制造商应适用第 6 节和第 7 节的规定。In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer shall apply the provisions of Sections 6 and 7.

13 制造商应组织并不断更新上市后监管计划，其中包括 PMCF 计划和确保遵守制造商义务的过程，详见第 VII 章警醒症与上市后监管体系规定。The manufacturer shall undertake to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII.

14 欧盟公告机构应根据第 15 条所述方法进行适当的检查和测试，以验证器械符合法规要求。The notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing every product as specified in Section 15.

本节第一段所述的检查和试验不适用于用于确保无菌条件的生产过程。The examinations and tests referred to in the first paragraph of this Section shall not apply to aspects of the manufacturing process designed to secure sterility.

15. 通过检查和测试验证器械的符合性 Verification by examination and testing of every product

15.1. 对各器械进行单独检查，应进行第 8 条相关标准中定义的适当物理试验或实验室试验或同等测试和评估，以确定器械符合 EC 型式检验证书中所说明的形式，且满足本法规中适用规定的要求（如适用）。Every device shall be examined individually and the appropriate physical or laboratory tests as defined in the relevant standard or standards referred to in Article 8, or equivalent tests and assessments, shall be carried out in order to verify, where appropriate, the conformity of the devices with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them.

15.2. 欧盟公告机构应在每台认可器械上贴上标识号，并根据所进行的测试和评估出具欧盟产品验证证书。The notified body shall affix, or have affixed, its identification number to each approved device and shall draw up an EU product verification certificate relating to the tests and assessments carried out.

16. 结合药物共同使用时，根据第 1(8)条器械可被视为作为整体部分的人血样或血浆源医药产品按批次进行验证 Batch verification in the case of devices incorporating, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in Article 1(8).

结合药物共同使用，根据第 1(8) 条第一子段可被视为作为整体部分的人血样或血浆源医药产品的器械生产完成后，制造商应通知欧盟公告机构器械批号，并向欧盟公告机构发送成员国实验室或根据第 2001/83/EC 号指令第 114(2) 节由成员国指定实验室颁发的使用人血液或血浆衍生物器械的官方证明。Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the

device, issued by a Member State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

17. 行政管理规定 Administrative provisions

制造商或其授权代表应在最后一个器械上市至少 10 年内（植入式器械为至少 15 年内），按照主管机构指示, 保管以下文件： The manufacturer or its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- EU 符合性声明； the EU declaration of conformity,
- 第 12 节所述文件, the documentation referred to in Section 12,
- 第 15.2 节所述证书, the certificate referred to in Section 15.2, and
- 附录 X 所述 EC 型式检验证书。 the EU type-examination certificate referred to in Annex X.

附录 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

18. 适用于 IIa 类器械 Application to class IIa devices

18.1. 通过豁免第 11 节，制造商可根据 EC 符合性, 确定并声明 IIa 类器械是否符合附录 II 和 III 所述技术文件, 以及是否满足本法规中的相应规定要求。 By way of derogation from Section 11, by virtue of the EU declaration of conformity the manufacturer shall be deemed to ensure and to declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

18.2. 由欧盟公告机构按照第 14 节进行的器械验证是用于确认 IIa 类器械是否符合附录 II 和 III 所述技术文件，以及是否满足本法规中的相应规定要求。 The verification conducted by the notified body in accordance with Section 14 is intended to confirm the conformity of the class IIa devices in question with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to them.

18.3. 如按照第 18.2 节进行验证, 结果确认 IIa 类器械是否符合附录 II 和 III 所述技术文件, 以及是否满足本法规中的相应规定要求，欧盟公告机构应根据本附录该节出具证明。 If the verification referred to in Section 18.2 confirms that the class IIa devices in question conform to the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this Part of this Annex.

18.4. 通过豁免第 17 节，制造商或其授权代表应在最后一个器械上市至少 10 年内，按照主管机构指示，保管以下文件：By way of derogation from Section 17, the manufacturer or its authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- EU 符合性声明； the EU declaration of conformity,
- 附录 II 和 III 所述技术文件, the technical documentation referred to in Annexes II and III, and
- 第 18.3 节所述证书。 the certificate referred to in Section 18.3.

附录 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

附录 **XII**

由公告机构签发的证书

CERTIFICATES ISSUED BY A NOTIFIED BODY

第 **I** 章 **CHAPTER I**

一般要求 GENERAL REQUIREMENTS

1. 应用欧盟的其中一种官方语言起草证书； Certificates shall be drawn up in one of the official languages of the Union.

2. 各证书均应仅参考一种符合性评估流程； Each certificate shall refer to only one conformity assessment procedure.

3. 证书应仅颁发给一家制造商证书中包含的制造商名称和地址应与在第 30 条中所述的电子系统中注册的信息相同； Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 30.

4. 证书适用范围的内容应明确说明所涵盖的器械： The scope of the certificates shall unambiguously identify the device or devices covered:

   (a) EU 技术文件评估证书、 EU 型式检验证书和 EU 产品验证证书应包含明确标识，包括器械名称、型号、类型、预期用途（制造商在使用说明中包含的并已通过符合性评估流程进行评定的预期用途） 、风险分类以及第 27(6)条所述的基本 UDI - DI 号； EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure, risk classification and the Basic UDI-DI as referred to in Article 27(6);

   (b) EU 质量管理体系证书和 EU 质量保证证书应包括器械标识或器械组别、风险分类和 IIb 类器械的预期用途； EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and, for class IIb devices, the intended purpose.

5. 公告机构应能够应要求说明证书所涵盖的（单一）器械。公告机构应说明能够确定证书所涵盖器械（包括其分类）的方法； The notified body shall be able to demonstrate on request, which (individual) devices are covered by the certificate. The notified body shall set up a system that enables the determination of the devices, including their classification, covered by the certificate.

6. 如适用，证书应包含本证书所涵盖器械的上市记录， 还需根据本法规颁发的另一证书； Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7. 根据第 52(7)条需要涉及公告机构的第 I 类器械的 EU 质量管理体系证书和 EU 质量保证证书应包含一份声明，声明公告机构已审核质量管理体系涉及该段中要求的方面。 EU quality management system certificates and EU quality assurance certificates for class I devices for which the involvement of a notified body is required pursuant to Article 52(7) shall include a statement that the audit by the notified body of the quality management system was limited to the aspects required under that paragraph.

8. 若本证书代替先前证书，即增补、修改或重新颁发证书时，新证书应包含先前证书的参考资料及其颁发日期以及变更标识。 Where a certificate is supplemented, modified or re-issued, the new certificate shall contain a

reference to the preceding certificate and its date of issue with identification of the changes.

第 II 章

证书的必需内容 MINIMUM CONTENT OF THE CERTIFICATES

1. 公告机构名称、地址和标识号； name, address and identification number of the notified body;
2. 制造商和授权代表（如适用）的名称和地址； name and address of the manufacturer and, if applicable, of the authorised representative;
3. 证书的唯一标识号； unique number identifying the certificate;
4. 第 31(2)条所述的制造商单一注册号； if already issued, the SRN of the manufacturer referred to in to Article 31(2);
5. 颁发日期； date of issue;
6. 失效日期； date of expiry;
7. 符合第 I 部分第 4 节规定的器械明确标识所需数据（如适用） ；data needed for the unambiguous identification of the device or devices where applicable as specified in Section 4 of Part I;
8. 如适用，参照在第 I 章第 8 节指定的先前证书； if applicable, reference to any previous certificate as specified in Section 8 of Chapter I;
9. 符合所进行符合性评估要求的本法规和相关附录参考资料； reference to this Regulation and the relevant Annex in accordance with which the conformity assessment has been carried out;
10. 所进行的检验和试验，例如相关 CS、协调标准、检验报告和审核报告的参考资料； examinations and tests performed, e.g. reference to relevant CS, harmonised standards, test reports and audit report(s);
11. 涵盖器械上市所需技术文件相关部分或其他证书的参考资料（如适用） ；if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered;
12. 公告机构的监管信息（如适用） ；if applicable, information about the surveillance by the notified body;
13. 公告机构针对相关附录的符合性评估结论； conclusions of the notified body's conformity assessment with regard to the relevant Annex;
14. 证书有效性的条件或限制； conditions for or limitations to the validity of the certificate;
15. 符合相关国家法律要求且具有法律约束力的公告机构签名。 legally binding signature of the notified body in accordance with the applicable national law.

附录 **XIII**

定制器械的步骤 **PROCEDURE FOR CUSTOM-MADE DEVICES**

1. 对于定制器械，制造商或其授权代表应起草声明，包含以下信息： For custom-made devices, the manufacturer or its authorised representative shall draw up a statement containing all of the following information:

   - 制造商的名称和地址，以及其他生产场所， the name and address of the manufacturer, and of all manufacturing sites,
   - 如适用，法定代表的姓名和地址， if applicable, the name and address of the authorised representative,
   - 标识问题器械的数据， data allowing identification of the device in question,
   - 声明器械经用于特定患者或使用者，按名称首字母缩写或数字代码标识， a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,
   - 由国家法律因其专业资格授权制定规定人士的姓名，及有关医疗机构的名称（如适用）， the name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned,
   - 规定中所述产品的具体特征， the specific characteristics of the product as indicated by the prescription
   - 声明问题器械符合附录 I 所述通用安全与性能要求，说明未完全符合的通用安全与性能要求（如适用），及理由， a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,
   - 该器械如欧盟委员会第 722/2012 号法规所述包含药械组合，人血液或血浆的衍生物，人或动物来源的组织或细胞， where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012. 。

2. 制造商应保证国家主管机构可随时查阅文档，说明生产场所，帮助理解产品的设计、生产和性能（包括预期性能），以便允许评估是否符合本法规要求进行评估。 The manufacturer shall undertake to keep available for the competent national authorities documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of this Regulation.

3. 制造商应采取一切必要的措施，确保依据生产工艺生产出的产品在生产过程中遵守第 2 节所述文件中的要求；The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2.

4. 本附录有关声明中所含信息应在器械上市后保存至少 10 年的时间。对于植入性器械，此期限应至少为 15 年。The statement referred to in the introductory part of Section 1 shall be kept for a period of at least 10 years after the device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

   附录 IX 第 8 节应适用。 Section 8 of Annex IX shall apply.

5. 制造商应承诺审查并记录在生产后阶段中获得的经验，包括附录 XIV 第 B 部分中所述的 PMCF，并采取适当的手段落实任何必要的纠正措施。该承诺应包括制造商在获悉任何严重事件和/或现场安全纠正措施之后，立即根据第 87(1)条向主管机构发送通知的义务。 The manufacturer shall review and document experience gained in

the post-production phase, including from PMCF as referred to in Part B of Annex XIV, and implement appropriate means to apply any necessary corrective action, In that context, it shall report in accordance with Article 87(1) to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them.

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附录 **XIV**

临床评价和上市后临床跟踪

CLINICAL EV ALUATION AND POST-MARKET CLINICAL FOLLOW-UP

第 **A** 部分：

临床评价 CLINICAL EVALUATION

1. 如需计划、不断进行并记录临床评价，制造商应： To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

(a) 建立并更新临床评价计划，该计划至少应包括： establish and update a clinical evaluation plan, which shall include at least:

- 标识通用安全与性能要求（需要相关临床数据的支持）；an identification of the general safety and performance requirements that require support from relevant clinical data;
- 器械的预期用途说明； a specification of the intended purpose of the device;
- 明确预期使用者以及明确适应症和禁忌症； a clear specification of intended target groups with clear indications and contra-indications;
- 对患者预期临床益处的详细说明以及相关和指定的临床结果参数； a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
- 检验临床安全性的定性和定量方面的方法说明，并明确说明对剩余风险和副作用的确定方法； a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
- 根据医学中最先进的技术确定器械各种适应症和预期用途的收益风险比的可接受性所使用的参数的指示性清单和说明； an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
- 如何解决特定方面（如药物、非活性动物或人体组织的使用）相关的风险利益问题的指示； an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed; and
- 一份用于指示从探索性研究（如首次人体研究、可行性研究、先导研究）到验证性研究（如关键的临床研究）进展过程的临床研发计划，以及符合本附录第 B 部分所述的 PMCF，此 PMCF 需列出里程碑并说明潜在验收标准； a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

(b) 确定器械相关的可用临床资料及其预期用途，以及通过系统的科学文献检索找到临床证据的缺口； identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;

(c) 通过评估临床数据在构建器械安全性和性能方面的适用性，对全部相关临床数据做出评价； appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

(d) 根据临床研发计划，通过合理设计的临床研究，生成解决现存问题所需的任何新的或额外的临床数据；

generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and

(e) 分析所有相关临床数据，以便得出器械的安全和临床性能（包括临床益处）方面的结论。 analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

2. 临床评价应深入且客观，并同时兼顾有利和不利数据。其深度和程度应与所述器械的性质、分类、预期用途、制造商有关该器械的声明和风险相称。 The clinical evaluation shall be thorough and objective, and take into account both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device.

3. 临床评价只能基于可证明与所述器械同等的相关器械的临床数据。在证明同等性的过程中应考虑以下技术、生物和临床特点： A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

- 技术特点：具有类似设计的器械；在类似条件下使用；具有类似规格和特性，包括物理化学特性，如能源强度、拉伸强度、粘度、表面特征、波长、软件算法等；使用类似部署方法（如相关）；具有类似工作原理和关键性能要求。 Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

- 生物特点：对于类似类型、类似接触时间和类似的物质释放特征，包括降解产物和可溶出物，该器械使用相同的材料或物质接触相同的人体组织或体液。 Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

- 临床特点：该器械用于同一临床情况或目的，包括类似的疾病严重程度和阶段，针对身体的同一部位，用于类似人群，包括年龄、解剖学和生理学；具有相同类型的使用者，具有根据预期临床效果得出的类似的针对某一特定预期用途的相关关键性能。 Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

第一段列出的特点的类似程度应使得器械的安全性和临床性能方面无显著的临床差异。对等同性的考虑必须始终基于合理的科学根据。为便于考察等同性，必须能够清楚地表明制造商有充分的条件获取具有等同性的相关器械上数据。 The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

4. 临床评价的结果和其所基于的临床证据应记录在临床评价报告中，而此报告应作为器械符合性评估的证明。 The results of the clinical evaluation and the clinical evidence on which it is based shall be documented in a clinical evaluation report which shall support the assessment of the conformity of the device.

临床证据和非临床检测方法得到的非临床数据以及其他相关文件一起，应足以允许制造商证明所述器械满足通

用安全与性能要求，并应加入所述器械技术文件中。 The clinical evidence together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation for the device in question.

临床评价中参考的有利和不利数据也应全部包含在技术文件中。 Both favourable and unfavourable data considered in the clinical evaluation shall be included in the technical documentation.

第 **B** 部分：

上市后临床跟踪 POST-MARKET CLINICAL FOLLOW-UP

5. PMCF 是一个更新本附录 A 部分第 61 条中所述的临床评价的持续过程，并应加入制造商上市后监管计划中。在进行 PMCF 时，制造商应主动收集并评估器械的临床数据，此器械应有 CE 标识，上市后或在相关符合性申请表评估流程中所述的其预期用途范围内投入使用，旨在验证在整个器械的预期使用寿命中器械的安全性和性能、确定已识别风险的持续可接受性， 以及旨在基于事实证据检测新出现的风险。 PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

6. PMCF 的执行应当遵循 PMCF 计划中规定并记录的方法。 PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.

6.1. PMCF 计划应规定方法和程序， 以便主动收集和评估临床数据， 旨在 The PMCF plan shall specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of:

(a) 确认器械在其预期使用寿命内的安全性和性能， confirming the safety and performance of the device throughout its expected lifetime,

(b) 识别之前未知的副作用并监控已识别的副作用和禁忌症， identifying previously unknown side-effects and monitoring the identified side-effects and contraindications,

(c) 在事实证据的基础上标识并分析突发风险， identifying and analysing emergent risks on the basis of factual evidence,

(d) 确保在附录 I 第 1 节和第 9 节中所述的收益 /风险比的持续可接受性，以及 ensuring the continued acceptability of the benefit-risk ratio referred to in Sections 1 and 9 of Annex I, and

(e) 确定器械可能的操作不当或超出标示使用，以验证其预期用途是否正确。 identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

6.2. PMCF 计划至少应包含： The PMCF plan shall include at least:

(a) 待采用的 PMCF 的通用方法和流程，如收集所获得的临床经验和使用者反馈，筛选科学文献和临床数据的其他来源； the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

(b) 待采用的 PMCF 的专用方法和流程，如对相应注册人员或 PMCF 研究的评估； the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

(c) （a）和（ b）中所述的方法和流程的适当理由； a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) 对第 4 节中所述的临床评价报告相关部分和附录 I 第 3 节中所述的风险管理的引用； a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I;

(e) 需通过 PMCF 完成的具体目标； the specific objectives to be addressed by the PMCF;

(f) 对等同或类似器械的相关临床数据的评估, an evaluation of the clinical data relating to equivalent or similar devices;

(g) 参考制造商使用的任何相关 CS、协调标准和 PMC F 相关指南。 reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and

(h) 对由制造商执行的 PMCF 活动（如对 PMCF 数据的分析和报告） 的详细且充分合理的时间安排。 a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

7. 制造商应分析 PMCF 的结果, 并在 PMCF 评估报告中记录结果, 而此 PMCF 评估报告应加入临床评价报告和技术文件中。 The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the clinical evaluation report and the technical documentation.

8. 和本附录第 A 部分第 61 条中所述的临床评价中以及附录 I 第 3 节中所述的风险管理中应考虑到 PMCF 评估报告的结论。 若通过 PMCF 确定了预防和 /或纠正措施的必要性, 则制造商应实施此等措施。 The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 61 and Part A of this Annex and in the risk management referred to in Section 3 of Annex I. If, through the PMCF, the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.

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附录 XV

临床研究 CLINICAL INVESTIGATIONS

第 I 章

一般要求 GENERAL REQUIREMENTS

1. 伦理学原则 Ethical principles

临床研究中的每一步，从首先考虑研究的必要性和正当性到公布结果，均应符合公认的伦理原则。Each step in the clinical investigation, from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.

2. 方法 Methods

2.1. 临床研究应在反映最新的科学和技术知识的适当研究方案的基础上进行，并进行定义以证实或驳斥第 62(1)条中所所述器械相关的安全性、性能和有关风险-收益要求的制造商声明；这些临床研究应有足够的观察数量，来保证结论的科学有效性。设计和选择的统计方法的基本原理应按照本附录第 II 章第 3.6 节中的进一步说明进行说明。Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims regarding the safety, performance and aspects relating to benefit-risk of devices as referred to in Article 62(1); the clinical investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions. The rationale for the design and chosen statistical methodology shall be presented as further described in Section 3.6 of Chapter II of this Annex.

2.2. 执行临床研究所用的流程应适合所研究的器械。The procedures used to perform the clinical investigation shall be appropriate to the device under investigation.

2.3. 执行研究所用的研究方法应适合所研究的器械。The research methodologies used to perform the clinical investigation shall be appropriate to the device under investigation.

2.4. 临床研究应由足够数量的预期使用者按照临床研究计划在可代表目标患者人群使用器械的预期正常条件的临床环境中执行。这些临床研究应与附录 XIV 第 A 部分中所述的临床评价计划一致。Clinical investigations shall be performed in accordance with the clinical investigation plan by a sufficient number of intended users and in a clinical environment that is representative of the intended normal conditions of use of the device in the target patient population. Clinical investigations shall be in line with the clinical evaluation plan as referred to in Part A of Annex XIV.

2.5. 器械的一切合适的技术和功能特征（特别是涉及安全性和性能方面的特征）以及其预期的临床结果的影响应由研究设计进行适当解决和检验。应提供一份列表，列明器械的技术和功能特征和相关预期的临床结果。All the appropriate technical and functional features of the device, in particular those involving safety and performance, and their expected clinical outcomes shall be appropriately addressed in the investigational design. A list of the technical and functional features of the device and the related expected clinical outcomes shall be provided.

2.6. 临床研究的终点应确定器械的预期用途、临床益处、性能和安全性。终点必须使用科学有效的方法来进行确定和评估。主要终点应与器械和临床相关性匹配。The endpoints of the clinical investigation shall address the intended purpose, clinical benefits, performance and safety of the device. The endpoints shall be determined and assessed using scientifically valid methodologies. The primary endpoint shall be appropriate to the device and clinically relevant.

2.7. 研究者应有权使用器械相关的技术和临床数据。参与研究的人员应接受关于正确使用试验用器械、临床研究计划和《医疗器械临床试验质量管理规范》方面的指导和培训。此等培训应予以核实，并（在必要时）由申办方安排并正确记录。 Investigators shall have access to the technical and clinical data regarding the device. Personnel involved in the conduct of an investigation shall be adequately instructed and trained in the proper use of the investigational device, and as regards the clinical investigation plan and good clinical practice. This training shall be verified and where necessary arranged by the sponsor and documented appropriately.

2.8. 由研究者签字的临床研究报告，应包括对临床研究过程中收集到的所有数据的严格评价，且应包括所有反向发现。The clinical investigation report, signed by the investigator, shall contain a critical evaluation of all the data collected during the clinical investigation, and shall include any negative findings.

第 II 章

临床研究申请表的有关文件 DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATIO

对于第 62 条中涵盖的试验用器械，申办方应当根据第 70 条之要求拟定申请表并与下列文件一起递交申请表： For investigational devices covered by Article 62, the sponsor shall draw up and submit the application in accordance with Article 70 accompanied by the following documents:

1. 申请表 Application form

申请表应填写完整，包含以下信息： The application form shall be duly filled in, containing information regarding:

1.1. 申办方的名称、地址和联系方式，和联系人 /根据第 62(2)条指定的其欧盟法定代理人的姓名、地址和联系方式（如适用）；name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with Article 62(2) established in the Union;

1.2. 临床研究器械的制造商和其授权代表 （如适用） 的名称、 地址和联系方式 （若第 1.1 节不适用）；if different from those in Section 1.1, name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of its authorised representative;

1.3. 临床研究的题目； title of the clinical investigation;

1.4. 临床研究申请表的状态（即第一次提交、再次提交和重大修改） ；status of the clinical investigation application (i.e. first submission, resubmission, significant amendment);

1.5. 临床评价计划的详情 /说明； details and/or reference to the clinical evaluation plan;

1.6. 关于同一器械，若重新提交之前已提交过的申请，则先前提交的先前日期和参考编号，或在重大修改的情况下，应参考原始申请。申办方应确定上次申请的所有变更以及该等变更的理由，特别是是否对以前的主管机构或伦理委员会审查结果进行了任何更改； If the application is a resubmission with regard to a device for which an application has been already submitted, the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application. The sponsor shall identify all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous competent authority or ethics committee reviews;

1.7. 若申请与根据第 536/2014 号法规的临床试验申请并行提交，请参考临床试验的正式注册号； if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial;

1.8. 申请表时作为多中心或多国研究的一部分而进行的临床研究所在成员国和第三国的标识信息； identification of the Member States and third countries in which the clinical investigation is to be

conducted as part of a multicentre or multinational study at the time of application;

1.9. 试验用器械的简要说明、分类和标识器械和器械类型所必要的其他信息； a brief description of the investigational device, its classification and other information necessary for the identification of the device and device type;

1.10. 器械是否使用药用物质，包括人体血液或血浆的衍生物，或者是否在生产时采用非活性人体或动物组织或细胞或其衍生物的相关信息； information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives;

1.11. 临床研究计划的总结，包括临床研究的对象、受试者的数量和性别、受试者选择标准、未满 18 周岁的受试者、研究的设计（如对照研究和 /或随机研究）以及开始和完成临床研究的计划日期） ；summary of the clinical investigation plan including the objective or objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation;

1.12. 若适用，关于比对器械的信息， 用于标识比对器械所必需的分类信息和其他信息； if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;

1.13. 申办方提供的证据，证明临床研究者和试验场所具备按照临床研究计划进行临床研究的能力； evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the clinical investigation plan;

1.14. 研究的预期开始日期和持续时间的详细信息； details of the anticipated start date and duration of the investigation;

1.15. 用于确定公告机构的详细信息，若在临床研究申请阶段已涉及； details to identify the notified body, if already involved at the stage of application for a clinical investigation;

1.16. 确认申办方知悉主管机构可与评估或已评估申请表的伦理委员会联系。 confirmation that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application; and

1.17. 第 4.1 节所述的声明。 the statement referred to in Section 4.1.

2. 研究者手册 Investigator's Brochure

研究者手册 （IB ）应包含与研究相关并在申请表时提供的试验用器械的临床和非临床信息。 对新出版的 IB 或其他相关信息的任何更新， 应及时提请研究者注意。 应明确标识 IB , 并特别包含以下信息： The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. Any updates to the IB or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. The IB shall be clearly identified and contain in particular the following information:

2.1. 器械的标识和说明，包括关于预期目的信息、根据附录 VIII 的风险分类和适用的分类规则、器械的设计和生产以及对前一代器械和类似器械的引用。 Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Annex VIII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. 制造商的安装、维护、维护卫生标准和使用说明（包括储存和处理要求） ，以及在提供此信息时，要贴在标签上的信息，以及在市售上时用于与器械一起提供的说明。此外，需要任何有关相关培训的信息。

Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed on the label, and instructions for use to be provided with the device when placed on the market. In addition, information relating to any relevant training required.

2.3. 临床前评估基于相关的临床前试验和实验数据，特别是设计计算、体外试验、半体内试验、动物试验、机械或电气试验、 可靠性试验、 灭菌验证、 软件验证和确认、 性能测试以及对生物相容性和生物安全性的评估（如适用）。Pre-clinical evaluation based on relevant pre-clinical testing and experimental data, in particular regarding in-design calculations, in vitro tests, ex vivo tests, animal tests, mechanical or electrical tests, reliability tests, sterilisation validation, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable.

2.4. 现有临床数据，特别是： Existing clinical data, in particular:

- 器械和 /或等同或类似器械的安全性、性能、患者的临床益处、设计特性和预期用途相关的现有相关科学文献； from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device and/or of equivalent or similar devices;
- 同一制造商的等同或类似器械的安全性、 性能、 患者的临床益处、 设计特性和预期用途相关的其他现有临床数据，包括上市时长与性能评价、临床效果与安全性相关问题以及采取的纠正措施； other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken.

2.5. 风险利益分析与风险管理的总结，包括已知或可预见的风险相关的信息、任何不良反应、禁忌症和警告。Summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings.

2.6. 对于药械组合的器械， 包括人体血液或血浆的衍生物， 或生产时利用非活性人体或动物组织或细胞或其衍生物， 该药物或者组织或细胞或其衍生物的详细信息， 或对通用安全与性能要求或药物、 组织或细胞或其衍生物相关的特定风险管理的遵从性的详细信息，以及掺入这些成分对关于器械的临床效果和 /或安全性的附加价值的证据。 In the case of devices that incorporate a medicinal substance, including a human blood or plasma derivative or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues, cells or their derivatives, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the device.

2.7. 详细说明附录 I 所列相关一般安全性和性能要求的列表， 包括全部或部分适用的标准和 CS，以及符合（或不符合 /仅部分符合这些标准和 CS/缺乏） 相关一般安全性和性能要求的解决方案说明。 A list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking.

2.8. 对临床研究过程中使用的临床流程和诊断测试的详细说明， 以及（特别是） 正常临床实践的任何相关偏差信息。 A detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.

3. 临床研究计划 Clinical Investigation Plan

临床研究计划（ CIP）应规定临床研究的理论基础、目标、设计和拟定分析、方法论、监控、执行、记录保存以及临床研究分析方法。其应特别包含本附录所述的信息。若这部分资料以一份单独文件的方式提交，应在 CIP 中说明。 The clinical investigation plan (CIP) shall set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation. It shall contain in particular the information as laid down in this Annex. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

3.1. 总则 General

3.1.1. 第 70(1)条所述的临床研究的唯一标识号。 Single identification number of the clinical investigation, as referred to in Article 70(1).

3.1.2. 根据第 62(2)条，提供来自欧盟的申办方的标识信息 —— 申办方联系人的名称、 地址和联系方式，或指定的其法定代理人的姓名、 地址和联系方式 （如适用）。Identification of the sponsor — name, address and contact details of the sponsor and, where applicable, the name, address and contact details of the sponsor's contact person or legal representative in accordance with Article 62(2) established in the Union.

3.1.3. 各试验机构的主要研究者以及协调研究者的信息、各试验机构的地址信息以及各机构主要研究者的紧急联系方式。各类研究者的任务、职责和资质应在 CIP 中做出规定。 Information on the principal investigator at each investigational site, the coordinating investigator for the investigation, the address details for each investigational site and the emergency contact details for the principal investigator at each site. The roles, responsibilities and qualifications of the various kinds of investigators shall be specified in the CIP.

3.1.4. 对临床研究费用的简要说明和对申办方与机构之间所达成协议的简要说明。 A brief description of how the clinical investigation is financed and a brief description of the agreement between the sponsor and the site.

3.1.5. 采用成员国确定的欧盟官方语言编写的临床研究概要； Overall synopsis of the clinical investigation, in an official Union language determined by the Member State concerned.

3.2. 器械的标识和说明（包括其预期用途、其制造商、其溯源性、其预期使用者、接触人体的材料、在其使用过程中涉及的医疗或外科手术、以及必要的使用培训和使用体验） 、新器械的背景文献综述、应用领域中临床医学的现有技术发展水平和拟议效果。 Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, background literature review, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device.

3.3. 待检验器械的风险和临床益处， 包括在临床研究计划中相应预期临床结果的适当证明。 Risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan.

3.4. 在临床实践的现有技术发展水平下对临床研究相关性的说明。 Description of the relevance of the clinical investigation in the context of the state of the art of clinical practice.

3.5. 临床研究的目标和假设。 Objectives and hypotheses of the clinical investigation.

3.6. 临床研究的设计，包括对其科学的可靠性和有效性的适当证明。 Design of the clinical investigation with evidence of its scientific robustness and validity.

3.6.1 基本信息，如研究的类型，并需说明临床评价计划中规定的各项选择、指标、变量的选用理由。General information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan.

3.6.2 临床研究中使用的试验用器械、 任何比对器械和任何其他器械或药物的相关信息。 Information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation.

3.6.3 受试者相关的信息、 选择标准、 研究人群的规模、 关于目标人群的研究人群代表， 以及（如适用）所涉及弱势受试者相关的信息，例如孕妇、儿童、免疫力低下者、老年人等） 。Information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects.

3.6.4 尽量减少偏差（例如随机化）需采取的措施和对潜在混杂因素的管理的详细信息。 Details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors.

3.6.5 对临床研究相关临床流程和诊断方法的说明，并特别突出与正常临床实践的任何偏差。 Description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice.

3.6.6 监测计划。 Monitoring plan.

3.7. 统计方面的考虑， 并说明其理由， 包括样本量的检验效能 （power）计算（如适用）。Statistical considerations, with justification, including a power calculation for the sample size, if applicable.

3.8. 数据管理。 Data management.

3.9. 对 CIP 的任何修改信息。 Information about any amendments to the CIP.

3.10. 在试验机构跟踪和管理与 CIP 的任何偏差以及明确禁止 CIP 豁免相关的政策。 Policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP.

3.11. 对器械的责任，特别是控制对器械的使用，对临床研究中使用器械的追踪以及退还未使用、注册到期或有故障的器械。 Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.

3.12. 遵守涉及人类的医学研究公认伦理原则、 《医疗器械临床试验质量管理规范》以及适用的法规要求的声明。 Statement of compliance with the recognised ethical principles for medical research involving humans, and the principles of good clinical practice in the field of clinical investigations of devices, as well as with the applicable regulatory requirements.

3.13. 对知情同意过程的说明。 Description of the Informed consent process.

3.14. 安全性报告， 包括对不良事件和严重不良事件的定义、 报告的器械缺陷、 流程和时间表。 Safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting.

3.15. 结束、暂时中断或提前终止研究之后对受试者进行跟踪、对撤回知情同意书的受试者进行跟踪，以及对失联受试者进行跟踪的准则和流程。对于植入性器械，此类流程必须包含可追溯性。 Criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up. Such procedures shall for implantable devices, cover as a minimum traceability.

3.16. 对临床研究结束后受试者照护安排的说明（当由于受试者对临床研究的参与使得额外照护很有必要时，或当情况偏离对所述医疗条件的正常预期时） 。A description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question.

3.17. 按照第 I 章第 1 节中所述的法律要求和伦理原则制定临床研究报告和公布结果方面的政策 Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.

3.18. 器械的技术和功能特征列表，列明研究所涵盖的技术和功能特征。 List of the technical and functional features of the device, with specific mention of those covered by the investigation.

3.19. 参考书目 。Bibliography.

4. 其他信息 Other information

4.1. 负责生产试验用器械的自然人或法人签字的声明，声明除了临床研究所涵盖的方面外，所述器械的其他方面均符合通用安全与性能要求，并声明对于临床研究所涵盖的方面，也已采取一切预防措施来保护受试者的健康和安全。 A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

4.2. 根据国家法律规定（如适用）提交的一份相关伦理委员会的意见副本。如根据国家法律规定，不需要在提交申请表时提交伦理委员会的意见时，应在获得后尽快提交一份伦理委员会的意见副本。 Where applicable according to national law, copy of the opinion or opinions of the ethics committee or committees concerned. Where according to national law the opinion or opinions of the ethics committee or committees is not required at the time of the submission of the application, a copy of the opinion or opinions shall be submitted as soon as available.

4.3. 在受试者受到人身伤害的情况下，根据第 69 条和相应的国家法律规定提交的投保或赔偿证明。 Proof of insurance cover or indemnification of subjects in case of injury, pursuant to Article 69 and the corresponding national law.

4.4. 用于获得知情同意书的文件，包括患者信息表和知情同意文件。 Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

4.5. 说明遵守关于个人资料保护和保密适用规则的安排，特别是： Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

- 将实施的组织和技术安排，以避免未经授权地访问、披露、传播、变更或丢失已处理的信息和个人数据； organisational and technical arrangements that will be implemented to avoid unauthorised

access, disclosure, dissemination, alteration or loss of information and personal data processed;

- 为确保受试者的记录和个人资料保密而将被实施的各项措施的说明； a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects; and

- 说明在数据安全漏洞的情况下将采取的措施, 以减少可能的不利影响。 a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

4.6. 技术文件的全部细节（例如详细的风险分析/管理文件或特定测试报告）应按要求提交给主管机构，以便其审查申请表。 Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports, shall, upon request, be submitted to the competent authority reviewing an application.

第 III 章

申办方的其他义务 OTHER OBLIGATIONS OF THE SPONSOR

1. 申办方应承诺继续向国家主管机构提供必需的任何文件，以便为本附录第 II 章中所述的文件提供证据。若申办方并非负责生产试验用器械的自然人或法人，则这一义务也可由申办方的法定代理人履行。 The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the investigational device, that obligation may be fulfilled by that person on behalf of the sponsor.

2. 申办方应达成一份协议，用来确保研究者及时向申办方报告第 80(2)条中所述的严重不良事件或任何其他事件。

The Sponsor shall have an agreement in place to ensure that any serious adverse events or any other event as referred to in Article 80(2) are reported by the investigator or investigators to the sponsor in a timely manner.

3. 本附录中所述的文件应在所述器械的临床研究结束后保存至少 10 年，或者若器械随后上市， 则应在最后一个器械上市至少 10 年内（植入式器械为至少 15 年内）妥善保存。 The documentation mentioned in this Annex shall be kept for a period of at least 10 years after the clinical investigation with the device in question has ended, or, in the event that the device is subsequently placed on the market, at least 10 years after the last device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years.

各成员国应要求， 本文件应保存第一子段所述明的期限以供主管机构处置， 以防申办方或其联系人或根据第 62(2)条指定的在其境内的法定代理人在此期限结束之前破产或停止其商业活动。 Each Member State shall require that this documentation is kept at the disposal of the competent authorities for the period referred to in the first subparagraph in case the sponsor, or its contact person or legal representative as referred to in Article 62(2) established within its territory, goes bankrupt or ceases its activity prior to the end of this period.

4. 申办方应任命一名独立于试验机构的监查员，以确保研究按照 CIP、《医疗器械临床试验质量管理规范》和本法规的原则进行。 The Sponsor shall appoint a monitor that is independent from the investigational site to ensure that the investigation is conducted in accordance with the CIP, the principles of good clinical practice and this Regulation.

5. 申办方应完成对研究受试者的跟踪。 The Sponsor shall complete the follow-up of investigation subjects.

6. 申办方应提供证据， 以确保研究按照 《医疗器械临床试验质量管理规范》 进行， 例如通过内部或外部检查。 The Sponsor shall provide evidence that the investigation is being conducted in line with good clinical practice, for instance through internal or external inspection.

7. 申办方应编写一份临床研究报告，该报告应至少包含以下内容： The Sponsor shall prepare a clinical investigation report which includes at least the following:

- 封面 /前言列出研究题目、试验用器械，唯一标识码、 CIP 数量和详细信息并由各试验场所协调研究者和主要研究者签字。 Cover/introductory page or pages indicating the title of the investigation, the investigational device, the single identification number, the CIP number and the details with signatures of the coordinating investigators and the principal investigators from each investigational site.
- 报告的作者和日期等详细信息。 Details of the author and date of the report.
- 研究总结应包括题目、研究目的、研究说明、所使用的研究设计和方法、研究结果和研究结论。研究的完成日期， 和（特别是）研究的提前终止、 中断或暂停的具体信息。 A summary of the investigation covering the title, purpose of the investigation, description of the investigation, investigational design and methods used, the results of the investigation and conclusion of the investigation. The completion date of the investigation, and in particular details of early termination, temporary halts or suspensions of investigations.
- 试验用器械的说明，特别是明确界定的预期用途。 Investigational device description, in particular clearly defined intended purpose.
- 临床研究计划总结应包括目标、设计、伦理方面、监控和质量措施、选择标准、目标患者人群、样本量、治疗方案、跟踪持续时间、伴随治疗、统计计划书，包括假设、样本量计算和分析方法以及正当性证明。 A summary of the clinical investigation plan covering objectives, design, ethical aspects, monitoring and quality measures, selection criteria, target patient populations, sample size, treatment schedules, follow-up duration, concomitant treatments, statistical plan, including hypothesis, sample size

calculation and analysis methods, as well as a justification.

- 临床研究的结果包括，依据和正当性证明、受试者人口统计学、对所选终点结果的分析、亚组分析的详细信息、对 CIP 的遵从性以及对丢失数据的跟踪和对退出研究/失联患者的跟踪。 Results of the clinical investigation covering, with rationale and justification, subject demographics, analysis of results related to chosen endpoints, details of subgroup analysis, as well as compliance with the CIP, and covering follow-up of missing data and of patients withdrawing from the clinical investigation, or lost to follow-up.

- 对严重不良事件、不良器械反应和器械缺陷以及任何相关的纠正措施的总结。 Summary of serious adverse events, adverse device effects, device deficiencies and any relevant corrective actions.

- 讨论和总体结论 —— 安全性和性能结果、风险和临床益处的评估，按照临床技术发展水平对临床相关性的讨论、特定患者人群的任何针对性预防措施，对试验用器械的影响和研究的局限性。 Discussion and overall conclusions covering safety and performance results, assessment of risks and clinical benefits, discussion of clinical relevance in accordance with clinical state of the art, any specific precautions for specific patient populations, implications for the investigational device, limitations of the investigation.

附录 **XVI**

在第 **1**（**2**）条中所述无预期医疗目的产品分组清单

LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

1. 预期用于放入眼睛内或放到眼睛上的隐形眼镜或其他物品； Contact lenses or other items intended to be introduced into or onto the eye.

2. 为修改解剖学或固定身体部位通过手术创伤的方式整体或部分放入人体内的产品，但纹身产品和穿孔产品除外； Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.

3. 预期通过皮下、粘膜下或皮内注射的方式或其他进入方式用于面部或其他皮肤或粘膜填充的物质、物质组合或物品，但不包括纹身所用的物质； Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.

4. 预期用于减少、去除或破坏脂肪组织的器械，如吸脂术、脂肪分解或抽脂所用的器械； Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

5. 发射高强度电磁辐射（例如，红外线、可见光和紫外线）用于在人体上进行磨皮、纹身或脱毛或其他皮肤治疗的器械，包括相干和非相干光源、单色光谱和广谱，如激光和强脉冲光器械； High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.

6. 预期使用电流或磁场或电磁场穿透颅骨来修改大脑中的神经元活动，以刺激脑部的器械。 Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

附录 **XVII**

对比表 **CORRELATION TABLE**

理事会第 **90/385/EEC** 号指令	理事会第 **93/42/EEC** 号指令	本法规
第 1(1)条	第 1(1)条	第 1(1)条
第 1(2)条	第 1(2)条	第 2 条
第 1(3)条	第 1(3)条第 1 子段	第 1(9)条第 1 子段
-	第 1(3)条第 2 子段	第 1(9)条第 2 子段
第 1(4)条和第（ 4a）条	第 1(4)条和第（ 4a）条	第 1(8)条第 1 子段
第 1(5)条	第 1(7)条	第 1(11)条
第 1(6)条	第 1(5)条	第 1(6)条
-	第 1(6)条	-
	第 1(8)条	第 1(13)条
第 2 条	第 2 条	第 5(1)条
第 3 条第 1 子段	第 3 条第 1 子段	第 5(2)条
第 3 条第 2 子段	第 3 条第 2 子段	第 1(12)条-
第 4(1)条	第 4(1)条	第 24 条
第 4(2)条	第 4(2)条	第 21(1)和(2)条
第 4(3)条	第 4(3)条	第 21(3)条
第 4(4)条	第 4(4)条	第 10(11)条
第 4(5)条（ a）	第 4(5)条第 1 子段	第 20(6)条
第 4(5)条（ b）	第 4(5)条第 2 子段	-
第 5(1)条	第 5(1)条	第 8(1)条
第 5(2)条	第 5(2)条	第 8(2)条
第 6(1)条	第 5(3)条，第 6 条	-
第 6(2)条	第 7(1)条	第 114 条
第 7 条	第 8 条	第 94 至 97 条
-	第 9 条	第 51 条
第 8(1)条	第 10(1)条	第 87(1)条和第 89(2)条
第 8(2)条	第 10(2)条	第 87(10)条和第 87(11)条第 1 子段
第 8(3)条	第 10(3)条	第 89(7)条
第 8(4)条	第 10(4)条	第 91 条
第 9(1)条	第 11(1)条	第 52(3)条
-	第 11(2)条	第 52(6)条
-	第 11(3)条	第 52(4)和（ 5）条
-	第 11(4)条	-
-	第 11(5)条	第 52(7)条
第 9(2)条	第 11(6)条	第 52(8)条

理事会第 **90/385/EEC** 号指令	理事会第 **93/42/EEC** 号指令	本法规
第 9(3)条	第 11(8)条	第 11(3)条
第 9(4)条	第 11(12)条	第 52(12)条
第 9(5)条	第 11(7)条	-
第 9(6)条	第 11(9)条	第 53(1)条
第 9(7)条	第 11(10)条	第 23(4)条
第 9(8)条	第 11(11)条	第 56(2)条
第 9(9)条	第 11(13)条	第 59 条
第 9(10)条	第 11(14)条	第 4(5)条和第 122 条第 3 段
-	第 12 条	第 22 条
-	第 12a 条	第 17 条
第 9a（1）条第一项	第 13(1)条（c）	-
第 9a（1）条第二项	第 13(1)条（d）	第 4(1)条
-	第 13(1)条（a）	第 51(3)条(a)和第 51(6)条
	第 13(1)条（b）	第 51(3)条(b)和第 51(6)条
第 10 条	第 15 条	第 62 至 82 条
第 10a(1)条、第 10a(2)条第 2 句和第 10a(3)条	第 14(1)条、第 14(2)条第 2 句和第 14(3)条	第 29(4)条、第 30 条和第 31 条
第 10a(2)条第 1 句	第 14(2)条第 1 句	第 11(1)条
第 10b 条	第 14a 条	第 33 和 34 条
第 10c 条	第 14b 条	第 98 条
第 11(1)条	第 16(1)条	第 42 条和第 43 条
第 11(2)条	第 16(2)条	第 36 条
第 11(3)条	第 16(3)条	第 46(4)条
第 11(4)条	第 16(4)条	-
第 11(5)条	第 16(5)条	第 56(5)条
第 11(6)条	第 16(6)条	第 56(4)条
第 11(7)条	第 16(7)条	第 38(2)条和第 44(2)条
第 12 条	第 17 条	第 20 条
第 13 条	第 18 条	第 94 至 97 条
第 14 条	第 19 条	第 99 条
第 15 条	第 20 条	第 109 条
第 15a 条	第 20a 条	第 102 条
第 16 条	第 22 条	-
第 17 条	第 23 条	-
-	第 21 条	-

欧洲议会和理事会于 2017 年 4 月 5 日签发的关于体外诊断医疗器械第 2017/746 号（EU）法规并废除了第 98/79/EC 号指令和委员会第 2010/227/EU 号决议（EEA 相关性文本）

欧洲议会和理事会,

考虑到“欧盟运作条约”，特别是其中第 114 条和第 168（4）（c）条之规定,

以及欧盟委员会之提案,

并于立法草案转交各国议会后,

考虑到欧洲经济和社会委员会之意见（[1]）,

在咨询地区委员之后,

根据一般立法程序运作（[2]）,

鉴于：

(1) 欧洲议会和理事会签发的第 98/79/EC 号指令（[3]）构成了欧盟体外诊断医疗器械监管框架。但需要对该指令进行大幅修订，以便建立稳健、透明、可预测和可持续的体外诊断医疗器械监管框架，以确保高水平的安全和健康，同时为创新提供支持。

(2) 本法规旨在确保区域内体外诊断医疗器械市场的顺利运作，在为患者和使用者提供高水平健康保护的基础上，同时考虑到活跃于本行业的中小型企业利益。同时，该法规为体外诊断医疗器械制定了高质量和安全性标准，以涵盖这些产品的常见安全问题。这两个目标相辅相成、不可分割地联系在一起，并且在达成过程中没有主次顺序。针对“欧盟运作条约”（TFEU）第 114 条，本法规协调了体外诊断医疗器械及其附件在欧盟市场上的上市和使用规则，而市场可允许其从货物自由流通原则中受益。针对 TFEU 第 168（4）（c）条，本法规通过确保性能研究中产生的数据的可靠性和稳健性,来保障体外诊断医疗器械的高质量和安全标准，并保障参与性能研究受试者的安全。

(3) 本法规并不寻求协调有关体外诊断医疗器械投入使用后，在市场上进一步供应之规则,例如二手销售。

(4) 应大大加强现有监管方法的关键要素，例如公告机构监管、风险分类、符合性评估流程、性能评估和性能研究、警戒和市场监管，同时引入确保体外诊断医疗器械透明度和可追溯性之规定，以改善健康和安全性。

(5) 如有可能，应当考虑到为体外诊断医疗器械制定的国际指导准则，特别是全球协调工作队及其后续行动即“国际医疗器械监管机构论坛（IMDRF）”，以便推动世界范围内利于提高安全防护标准以及促进贸易之相关法规的全球化进程，特别是关于唯一器械标识、通用安全与性能要求、技术文件、分类标准、符合性评估流程和临床证据等方面的规定。

（[1]）2013 年 2 月 14 日意见（OJ C 133, 9.5.2013, p.52）。

（[2]）2014 年 4 月 2 日的欧洲议会立场（尚未在官方公告内公布）以及 2017 年 3 月 7 日首次审阅时理事会的立场（尚未在官方公告内公布）。

（[3]）欧洲议会和理事会于 1998 年 10 月 27 日签发之关于体外诊断医疗器械第 98/79/EC 号指令（OJ L 331, 7.12.1998, p.1）。

(6) 体外诊断医疗器械本身存在一些具体特征，例如风险分类、符合性评估流程和临床证据等，而体外诊断医疗器械行业（该行业不同于其他医疗器械，需要特殊立法）同样如此，因此两个领域共通内容应当协调一致。

(7) 本法规的适用范围应与产品其他立法明确区分，例如医疗器械、一般实验室用产品和仅供研究使用产品（ RUO）。

(8) 成员国有责任逐案例确认，各产品是否属于本法规范围。为确保所有成员国的相关判断力一致，特别是在灰区临界情况下，在咨询医疗器械协调小组（ MDCG ）后，应允许委员会主动或经成员国适时且有根据地请求，逐案决定某一具体产品、类别或产品组是否属于本法规适用范围。在审议涉及药品、人体组织和细胞、生物灭活产品或食品之临界案例所辖产品之监管状况时，委员会应确保欧洲药品管理局、欧洲化学品管理局和欧洲食品安全局的适当咨询水平。

(9) 不同国家关于基因检测的信息提供和咨询之规则似乎仅能在有限程度上影响内部市场的顺利运作。因此，为确保始终遵守适当和辅助性原则，本法规仅在这方面规定了有限要求。

(10) 应明确指出，提供关于某种医疗状况或疾病的疾病倾向信息的所有测试（例如基因检测）以及提供用于提供疗效预测信息的测试（如伴随诊断）均属于体外诊断医疗器械。

(11) 伴随诊断的重要性在于，通过定量或定性测定某特定标记物来判断受试者是否适合某种药物特异性治疗，所述标记物可识别出对特定药品产生不良反应之高风险受试者，或识别出治疗产物经过充分研究，发现可安全有效适用之患者群体。此等生物标记物也可能存在于健康受试者和 /或患者中。

(12) 为确保人体中相关物质浓度处于治疗窗口内，而监控某一医疗产品疗效的器械，不可视为伴随诊断。

(13) 应考虑公认的现有医药领域技术水平来实现尽可能降低风险要求。

(14) 欧洲议会和理事会第 2014/30/EU 号指令 （[1]）涵盖的安全问题属于本法规中器械通用安全与性能要求的一部分。因此，本法规应被视为与该指令有关的特别法。

(15) 本法规应包括关于设计和制造发射电离辐射器械之要求，但不影响理事会第 2013/59/Euratom 号指令（ [2]）之适用范围（旨在达成其他目标） 。

(16) 本法规包括考虑到防止职业伤害的器械之安全与性能特性相关要求， 包括辐射防护。

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(1) 欧洲议会和理事会于 2004 年 2 月 26 日签发之关于电磁兼容性的成员国协调法案的第 2014/30/EU 号指令（ OJ L96, 29.3.2014, p.79 ）。

(2) 委员会于 2013 年 12 月 5 日签发之第 2013/59/Euratom 号指令规定了防止因电离辐射引起危险之基本安全标准，并废除了第 89/618/Euratom 、 90/641/Euratom 、 96/29/Euratom 、 97/43/Euratom 和 2003/122/Euratom5 等标准（ OJ L13, 17.1.2014, p.1 ）。

(17) 有必要明确的是，当制造商的软件专用于体外诊断医疗器械定义中所述的一种或多种医学目的时，软件本身可视为体外诊断医疗器械，而用于一般目的的软件，即使在医疗保健环境中使用，或用于健康应用之软件，均不视为体外诊断医疗器械。作为器械或附件之软件的资格评定不得依赖于这个软件和器械之间的物理位置或互连类型决定。

(18) 本法规中，关于器械本身、器械供应、经济运营商、使用者和具体过程、符合性评估、临床证据、上市后监管、警戒和市场监管、标准和其他技术规范等定义应当符合欧盟和国际上本领域的既定做法，以提高法律确定性。

(19) 应明确指出，通过欧洲议会和理事会第 2015/1535 号指令（[1]）中所规定的信息服务，向欧盟人员提供的器械以及在商业活动范围内用于为欧盟内人员提供诊断或治疗服务的器械，当在欧盟境内上市或提供服务时，必须符合本法规要求。

(20) 为认识到标准化在体外诊断医疗器械领域中的重要作用，符合欧洲议会和理事会第 1025/2012 号法规（[2]）中规定的协调标准之相关证据，应是制造商证明其产品符合通用安全与性能要求以及其他法律要求（如本法规所述质量和风险管理）的手段。

(21) 第 98/79/EC 号指令，允许委员会对特定类别体外诊断医疗器械采用通用技术规范。在没有协调标准或协调标准不够充分的地区，委员会应有权制定规范，以规定符合通用安全与性能要求的手段，以及本法规要求之性能研究和性能评估和 /或上市后跟踪的相关要求。

(22) 在咨询相关利益相关者并考虑欧洲和国际标准后，应制定通用规范（ “ CS ”）。

(23) 适用于器械的规则应酌情与“ 产品营销新立法框架 ”保持一致，其中包括欧洲议会和理事会第 765/2008 号法规（[3]），和欧洲议会和理事会第 768/2008/EC 号决议（[4]）。

(24) 针对进入欧盟市场的产品，欧洲委员会第 765/2008 号法规规定的欧盟市场监管和控制规则，同样适用于本法规所涵盖的器械，但这不妨碍成员国自行选择主管机构来执行这些任务。

(25) 根据“ 产品营销新立法框架 ” ，在不影响本法规不同部分规定的具体义务的情况下，明确规定不同经济运营商（包括进口商和经销商）的一般义务，加强对本法规要求的理解，从而提高相关运营商的法规符合性。

(26) 就本法规而言，经销商的活动应视为包括获取、持有和供应器械。

（[1]）欧洲议会和理事会于 2015 年 9 月 9 日签发的关于在信息服务技术标准和法规领域提供信息的流程的第 2015/1535 号指令（ OJ L 241, 17.9.2015, p.1）。

（[2]）欧洲议会和理事会于 2012 年 10 月 25 日签发的有关欧洲标准化的第 1025/2012 号指令，修订了欧洲理事会第 89/686/EEC 和 93/15/EEC 号指令以及欧洲议会和理事会第 94/9/EC、 94/25/EC、 95/16/EC、 97/23/EC、 98/34/EC、2004/22/EC、 2007/23/EC、2009/23/EC 和 2009/105/EC 号指令，并废除了欧洲理事会第 87/95/EEC 号决议和欧洲议会和理事会第 1673/2006/EC 号决议（ OJ L 316, 14.11.2012, p. 12）。

（[3]）欧洲议会和理事会于 2008 年 7 月 9 日签发的关于与产品营销有关的认证和市场监管的要求的第 765/2008 号法规，废除了第 339/93 号法规 (OJ L 218, 13.8.2008,p. 30).

（[4]）欧洲议会和理事会于 2008 年 7 月 9 日签发的关于产品营销通用框架的第 768/2008/EC 号决议，并废除理事会第 93/465/EEC 号决议（ OJ L 218, 13.8.2008, p. 82）。

(27) 制造商的一些义务，例如性能评估或警戒报告，仅为第 98/79/EC 号指令的附录中列出之内容，这些应纳入本法规颁布条款中，以便于应用。

(28) 为确保最高健康保护水平，应澄清并强化关于生产和使用仅在单一健康机构内使用的体外诊断医疗器械的相关规定。这一用途应理解为包括如何测定以及结果报告。

(29) 卫生机构应可内部（而不是在工业规模上）制造、修改和使用器械，从而解决目标患者群体的具体需求，这些需求往往无法通过市场上适当性能水平的等效器械来满足。在这种情况下，适当的做法是在本法规中规定特定条款的豁免，这就是关于仅在卫生机构（含医院以及支持卫生保健系统和 /或解决患者需求但可能不会直接治疗或照顾患者之实验室和公共卫生机构等）内部制造和使用器械的豁免条例，这样本法规就可以适当方式予以满足。应注意，卫生机构的概念不包括主要追求健康利益或健康生活方式的机构，例如健身房、水疗中心、健康与健身中心。因此，适用于卫生机构的豁免条例不适用于这些机构。

(30) 鉴于自然人或法人可根据适用的欧盟和国家法律， 就缺陷器械造成的损害提出索赔，因此， 可要求制造商采取适当措施， 就其在第 85/374/EEC 号指令（[1]）规定的潜在责任提供足够的保险范围。这些措施应与器械的风险等级、类型和企业规模成比例。在本文中，还应规定有关主管机构向可能因缺陷器械而受伤人员提供信息的规则。

(31) 为确保批量生产的器械继续符合本法规的要求，并且将生产的器械的使用经验纳入生产过程中，所有制造商均应具备质量管理体系和上市后监管体系，此类系统应与上述器械的风险级别和分类对应。此外，为尽可能降低器械相关的风险或防止与之相关事故的发生，制造商应建立风险管理体系，以及报告事故和现场安全纠正措施的系统。

(32) 风险管理体系应与器械的性能评估过程保持一致，并在该评估过程中反映，包括作为性能研究、性能评估和上市后性能跟踪的一部分需解决的临床风险。风险管理和性能评估过程应相互依存，并应定期更新。

(33) 应确保由器械制造商组织内部负责法规符合性的人员（该人员符合最低资格条件） ，进行与之相关的制造以及上市后监管和警戒活动的监督和控制。

(34) 对于欧盟以外的制造商，授权代表在确保此类制造商生产的器械符合性，以及作为其在欧盟建立的联系人方面发挥关键作用。鉴于这种关键作用，若欧盟以外的制造商未遵守其一般义务，出于执法目的，其授权代表依然应当对有缺陷的器械负法律责任。本法规规定的授权代表的法律责任并不影响第 85/374/EEC 号指令的规定，因此授权代表应对进口商和制造商承担连带责任。应在书面指令中确定授权代表的职责。鉴于授权代表的角色，应明确规定其应满足的最低要求，包括提供满足最低资格条件的人员的要求，此类资格条件应与制造商处负责法规符合性的人员的资格条件类似。

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(1) 委员会于 1985 年 7 月 25 日签发的有关成员国缺陷产品责任的相似法律、法规和行政规定的第

85/374/EEC 号指令（ OJ L 210, 7.8.1985, p. 29）。

(35) 为确保经济运营商义务的法律确定性，有必要说明何时将经销商、进口商或其他人视为器械制造商。

(36) 根据“ 欧盟运作条约（ TFEU ）”第 34 条的规定，（该规定以 TFEU 第 36 条规定的健康和安全保护需求以及知识产权保护需求带来的限制性规定为准）已经投放市场的产品的平行贸易是内部市场的一种合法贸易形式。但这一平行贸易原则的适用性受成员国的不同解释的制约。因此，应在本法规中特别规定重贴标和重包装的要求，同时考虑到其他相关行业的法院案例法（ [1]）和体外诊断医疗器械领域的现有良好实践。

(37) 一般来说， 器械应具有 CE 标识， 表明其符合本法规， 以便其在欧盟内自由流通并根据其预期目的投入使用。成员国不得对符合本法规规定要求的器械，在其投放市场或投入使用方面制造障碍。不过，应允许成员国决定是否限制使用本法规未涵盖的任何特定类型的器械。

(38) 由于改进的事故报告、 有针对性的现场安全纠正措施以及主管机构更好的监督机制，通过基于国际指导的唯一器械标识系统（ UDI 系统）实现的器械的可追踪性，应显著提高器械上市后安全相关活动的有效性。这归功于减少的医疗失误，以及对虚假器械的打击。 UDI 系统的应用还应改善卫生机构和其他经济运营商的采购和废物处置政策以及库存管理，并在可能的情况下，与这些设置中存在的其他验证系统兼容。

(39) UDI 系统应适用于市场上的所有器械（除用于性能研究的器械之外） ，并基于国际公认的原则，包括与主要贸易伙伴相一致的定义。为使 UDI 系统及时起作用，以免影响本法规生效，应在本法规和欧洲议会和理事会第 2017/745 号法规（ [2]）做出详细规定。

(40) 为保护公众健康，赋予患者和医疗保健专业人员自主权以及确保其能够做出明智的决定，为向监管决定制定提供一个稳妥的基础，确保为预期使用者提供的信息的透明度和充分性对于公众利益至关重要。

(41) 为达成本法规目标，其中一个关键点是建立欧洲医疗器械数据库（ Eudamed），该数据库应整合不同的电子系统，以核对和处理关于上市的体外诊断医疗器械以及相关经济运营商、符合性评定问题、公告机构、证书、性能研究、警戒和后市场监管等相关信息。数据库的目标是提高总体透明度，包括通过更好地为公众和卫生保健专业人员提供信息，以避免多重报告要求、加强成员国之间的配合、简化和促进经济运营商、公告机构或申办方和成员国之间的信息流通，以及成员国之间和欧盟委员会之间的信息流通。在内部市场中，只能在欧盟级别有效确保这一点，因此欧盟委员会应进一步开发和管理委员会第 2010/227/EU 号决议（[3]）设置的医疗器械数据库。

(42) 为促进欧洲医疗器械数据库 （Eudamed）的运作， 国际公认的医疗器械命名应免费提供给制造商和其他自然人或法人，且本法规要求相关人员必须使用该命名。此外，在合理可行的情况下，也应向其他利益相关者免费提供此类命名。

（[1]）2011 年 7 月 28 日法院对案件 C - 400/09 和 C - 207/10 的判决， ecli:eu:c:2011:519。

（[2]）欧洲议会和理事会于 2017 年 4 月 5 日签发的关于医疗器械第 2017/745 号法规，修订第 2001/83/EC 号法规、欧盟第 178/2002 号法规以及第 1223/2009 号法规，并废除理事会第 90/385/EEC 号指令和第 93/42/EEC 号指令（详见《官方公报》第 1 页）。

（[3]） 委员会于 2010 年 4 月 19 日就欧洲医疗器械数据库签署的第 2010/227/EU 号决议（OJ L 102, 23.4.2010,

p. 45）。

(43) Eudamed 关于市场上的器械，相关经济运营商和证书的电子系统应确保公众充分了解欧盟市场上的器械。性能研究电子系统应作为工具，确保成员国之间合作，以及申办方能够在自愿基础上向若干成员国提交单项申请，并报告严重不良事件、器械缺陷和相关更新。电子警戒系统应确保制造商能够报告严重事件和其他异常事件，并支持主管机构协调此等事故和事件的评估。市场监管相关电子系统应作为主管机构之间进行信息交流的工具。

(44) 关于通过 Eudamed 电子系统核对和处理的数据， 欧洲议会和理事会第 95/46/EC 号指令（[1]）适用于在成员国主管机构（特别是成员国指定的公共独立机构）的监督下，由成员国进行个人数据处理。欧洲议会和理事会第 45/2001 号法规（[2]）适用于在欧洲数据保护管理程序的监督下，由委员会在本法规框架内处理个人数据。根据第 45/2001 号指令，应指定委员会作为 Eudamed 及其电子系统的管理者。

(45) 对于 C 类和 D 类器械，制造商应在公开提供的文件中总结器械的主要安全与性能方面以及性能评估的结果。

(46) 公告机构的正常运作对于确保高水平的健康和安全保护以及公民对系统的信心至关重要。因此，成员国根据详细和严格的标准对指定机构进行的指定和监测，应在欧盟级别实行控制。

(47) 公告机构 对制造商的技术文件的评估，特别是其性能评估文件，应由负责公告机构的主管机构进行严格评估。此类评估是一种基于风险的手段，用于监督和监测公告机构活动，评估时可采取相关文件抽样的方法。

(48) 应加强公告机构对制造商的监管，包括其进行突击飞行检查和对器械进行物理或实验室测试的权利和义务，以确保制造商在收到原始证书后持续合规。

(49) 为提高国家主管机构监督公告机构的透明度，公告机构的主管机构应公布其用于指定和监测器械公告机构的国家评估监管措施的信息。根据良好的行政实践，主管机构应该及时更新这些信息，特别是反映上述流程的相关、重大或实质性变更。

(50) 公告机构所在的成员国应负责执行本法规关于该公告机构的要求。

(51) 特别是考虑到成员国组织并提供保健服务和医疗护理的责任，允许其制定有关公告机构的其他要求，此类机构用于器械的符合性评估，并且基于本法规未规定问题的领域。规定的此等额外要求不会影响欧盟针对公告机构更为具体的横向欧盟立法和对公告机构的平等对待。

(52) 对于 D 类器械，公告机构应向主管机构通报公告机构颁发的证书，并授权主管机构审查由公告机构出具的评估报告。

（[1]） 1995年 10 月 24 日欧洲议会和理事会关于保护个人在处理个人数据和数据自由流通方面的第 95/46/EC 号指令（OJ L 281, 23.11.1995, p.31）。

（[2]） 2000年 12 月 18 日欧洲议会和理事会关于保护个人在欧共体机构和机构处理个人数据自由流通方面的第 45/2001 号法规（ OJ L8, 12.1.2001, p. 1）。

(53) 对于无 CS 的 D 类器械，若是首创的器械，市场上无类似产品具有相同预期用途和检验原理的特定类型器械，除了针对制造商声称的性能进行检测和在欧盟参考实验室检测试剂的符合性之外，公告机构有义务要求专家小组审查其性能评估与评定报告。专家小组对于性能评估咨询应通过分享性能方面的专业知识并制定关于经历此类查阅过程的器械类别的 CS，促进高风险体外诊断医疗器械的协调评估。

(54) 为保证患者安全并适当考虑技术进步，应当根据国际惯例从根本上改变目前根据第 98/79/EC 号指令制定的器械的分类系统，并调整相应的符合性评估流程。

(55) 根据符合性评估流程需要，必须将器械分为四个风险级别，并根据国际惯例建立一套健全的基于风险的分类规则。

(56) 一般情况下，应由制造商全权负责 A 类器械的符合性评估流程，因为此类器械对患者造成危害的风险较低。对于 B、C 和 D 类器械，应强制要求公告机构适当程度地参与。

(57) 应进一步加强和简化器械符合性评估流程，同时应明确规定公告机构对其评估执行情况的要求，以确保公平竞争的环境。

(58) 自由销售证书包含的信息，应该有助于使用 Eudamed，以便获得器械的信息，无论器械是否上市，从市场撤出或召回，以及具备何种合格证。

(59) 必须说明关于最高风险器械批签发验证的要求。

(60) 当存在 CS，或由制造商选择其他方案，该方案应确保安全水平与性能不低于 CS 时，欧盟参考实验室应具备相应的检验能力，以验证存在高风险的器械是否符合适用 CS 要求。

(61) 为确保高水平安全与性能，符合本法规规定的通用安全与性能要求的证明应基于临床证据。必须说明临床证据的证实要求应基于科学有效性的数据，分析性能评估资料以及临床性能。为获得一个结构化和透明的流程，生成可靠稳定的数据，获取与评估可用的科学信息与性能研究得到的数据等应基于性能评估计划。

(62) 一般来说，临床证据应获取自申办方负责的性能研究。应当能够由制造商和另一法人或自然人负责性能研究。

(63) 必须确保在器械整个生命周期内对其临床证据进行更新。此等更新需要制造商定期监控医疗实践的科学发展和变化。然后，相关的最新信息应当促使对器械的临床证据的重新评估，从而通过连续的性能评估过程确保安全与性能。

(64) 应当认识到，体外诊断医疗器械临床效益的概念与药物或治疗性医疗器械临床效益的概念完全不同，因为体外诊断医疗器械的优势在于提供关于患者的准确医疗信息，并在适当时评估通过使用其他诊断方法和技术获得的医疗信息，而患者的最终临床结果取决于可用的进一步的诊断和/或治疗方法。

(65) 若特定的器械无分析性能或临床性能又或特定性能要求不适用，则需在性能评估计划和相关报告中证明与此等要求相关的缺失是合理的。

(66) 性能研究规则应符合本领域成熟的国际指导原则，例如关于人类受试者医疗器械临床研究的临床试验质量管理规范（ ISO 国际标准 14155:2011），以促使将在欧盟内进行的性能研究结果成为欧盟境外得到认可的文件规范，并促使根据国际准则在欧盟之外进行的性能研究结果可在欧盟内获得认可。此外，这些规则应符合世界医学协会《赫尔辛基宣言》关于涉及人类受试者医学研究伦理原则的最新版本。

(67) 应由开展性能研究的成员国决定参与评估申请进行性能研究的适当管理机构，并组织伦理委员会在本法规设定的性能研究授权的时间期限内参与。这些决定属于各成员国的内部组织问题。在这种情况下，成员国应确保非专业人员，特别是患者或患者组织的参与。此外，其还应确保提供必要的专门知识。

(68) 应在欧盟级别创建电子系统，以确保在可公开访问的数据库中记录和报告各干预性临床性能研究和涉及研究的受试者风险的其他性能研究。为保护“ 欧盟基本权利宪章 ”（简称“ 宪章 ”）第 8 条承认的个人资料保护权，不得在电子系统中记录参与性能研究的受试者的个人资料。为确保与医药产品临床试验领域的协同作用，性能研究的电子系统应该与用于人用药品的临床试验的欧洲数据库互通。

(69) 若干预性临床性能研究或涉及受试者风险的另一项性能研究将在多个成员国进行，申办方应有机会提交单项申请，以减轻行政负担。为允许资源共享并确保用于性能研究的器械以及性能研究的科学设计在卫生安全方面的一致性，这种单项申请的评估流程应在成员国之间在协调成员国指导下进行协调。协调评估不得包括对性能研究的国家、地方和伦理方面的评估，包括知情同意。对于自法规生效之日起的前七年，成员国应能够自发参加协调评估。在这一时期过后，所有相关成员国应有义务参加这一协调评估。委员会应基于从成员国之间的自发性协调获取的经验，应当制定一份报告，介绍涉及到协调评估流程的相关规定的应用。一旦报告结论是否定的，则欧盟委员会应提交一份提案，以延长自愿参与协调评估流程的期限。

(70) 申办方应向开展研究的成员国报告干预性临床性能研究期间发生的某些不良事件和器械缺陷以及涉及受试者风险的其他性能研究。若认为必要，成员国可终止或暂停此类研究或者吊销这些研究的授权，以确保为此类研究中的参与受试者提供高水平的保护。这些信息应该传达给其他成员国。

(71) 性能研究申办方应在适当时间内，为预期使用者提供易于理解的性能研究的结果总结，以及性能研究报告（如适用） 。若由于科学原因不能在本法规规定的时间内提交结果总结，申办方应证明这一点，并表明何时提交结果。

(72) 由于一些一般要求的免除，本法规应仅涵盖旨在收集科学数据并证明器械符合性目的之性能研究。

(73) 必须说明使用剩余标本的性能研究不需要授权批准。不过，关于数据保护的一般要求和其他附加要求以及适用于根据各国法律（如伦理审查）执行的流程要求，同样适用于所有性能研究 ，包括使用剩余样本的研究。

(74) 应遵守欧洲议会和理事会第 2010/63/EU 号指令（[1]）中所规定的动物实验领域的替换、减少和完善原则。特别是，应避免不必要的重复测试和研究。

(75) 制造商应在售后阶段发挥积极作用，通过系统和积极地根据其器械售后体验收集信息，以更新其技术文件，并与负责警戒和市场监管活动的国家主管机构合作。为此，制造商应根据质量管理体系并基于上市后监管计划，建立一个综合的上市后监管体系。且应借助在上市后监管中收集的相关数据和信息，以及从任何执行的预防和 /或纠正措施中吸取的经验教训，更新技术文件的任何相关部分，如风险评估相关文件和性能评估，还应确保文件透明度。

(76) 为更好地保障上市器械相关健康和安全问题，应当通过创建欧盟级别的中央门户网站报告严重事件和现场安全纠正措施，使得用于器械的电子警戒系统更有效。

(77) 成员国应采取适当措施，提高医护专业人员、使用者和患者对报告事件的重要性的认识。应该鼓励医护专业人员、使用者和患者使用统一格式在国家级别报告可疑的严重事件。国家主管机构应通知制造商任何疑似严重事件，并且当制造商确认此等事故发生时，相关主管机构应确保采取适当的跟踪措施，以尽量避免此类事件的再次发生。

(78) 应在国家级别评估报告的严重事件和现场安全纠正措施，但应确保在类似事件发生时进行协调，或者必须在多个成员国进行现场安全纠正措施，目的是共享资源并确保纠正措施的一致性。

(79) 在事故调查背景中，主管机构应酌情考虑利益相关者（包括患者和医护专业人员组织和制造商协会）提供的信息和意见。

(80) 应清楚区分涉及受试者风险的干预性临床性能研究和其他性能研究中的严重不良事件或器械缺陷报告与器械投放市场之后发生的严重事件的报告，以避免重复报告。

(81) 本法规应包含市场监管规则，以加强国家主管机构的权利和义务，确保市场监管活动的有效协调，并说明适用的流程。

(82) 可能对风险利益分析产生重大影响，并且可能导致不可接受风险的，不严重或预期副作用事件，如数量或严重程度出现显著增加，均应向主管机构报告，以允许其进行评估和采取适当的措施。

(83) 委员会应当基于欧盟第 2017/745 号法规定义的条件和模式成立一个由成员国指派的专家（根据其在医疗器械（包括体外诊断医疗器械）领域中的职务和专长）组成的专家委员会委员会（ MDCG ），应根据创建，以完成本法规和欧洲议会和理事会第 2017/745 号法规赋予该小组的使命，向委员会提供建议，以及协助委员会和成员国确保本法规的协调实施委员会委员会。 MDCG 应当能够建立其分小组， 以便在医疗器械（包括体外诊断医疗器械）领域提供必要的、有见地的专门技术知识。在建立分小组时，应适当考虑在医疗器械领域中加入现有欧盟级别团体的可能性。

([1]) 欧洲议会和理事会于 2010 年 9 月 22 日签发关于保护用于科学目的之动物的第 2010/63/EU 号指令（OJ L 276, 20.10.2010. p. 33）。

(84) 通过在协调机构的指导下的信息交流和协调评估，国家主管机构之间进行的更密切的协调，对于确保内部市场，特别是在性能研究和警戒领域的统一高水平的健康和安全保护至关重要。协调交流和评估的原则也应适用于本法规中说明的其他机构活动，例如公告机构名称，并应在器械的市场监管领域中鼓励使用该原则。活动的协作、协调和沟通也应在国家层级上引领更有效地利用资源和专门知识。

(85) 委员会应向协调国家主管机构提供科学、技术和相应的后勤支持，并确保器械的监管制度在欧盟层级基于可靠的科学证据能够得以有效且统一地实施。

(86) 欧盟及成员国应酌情积极参与器械领域的国际监管合作，以促进有关器械安全相关信息的交流，并促进国际监管准则的进一步发展，从而推动其他法规司法管辖区采用与本法规所规定卫生与安全保障水平同等的法规。

(87) 成员国应采取一切必要措施，确保本法规的规定得到执行，包括针对违反行为制定有效、相称和劝诫性的处罚。

(88) 同时，本法规不得影响成员国对国家一级活动征收费用的权利，但成员国在决定相关费用级别和结构之前应通知欧盟委员会和其他成员国，以确保透明度。为进一步确保透明度，应根据要求公开费用结构和级别。

(89) 本法规尊重基本权利，并遵守《宪章》所认可的原则，尤其是人类尊严、人身完整性、个人资料的保护、艺术和科学自由、开展业务的自由和财产权。成员国应根据这些权利和原则应用本法规。

(90) 根据 TFEU 第 290 条，应当授予委员会批准授权法案的权限，以便修订本法规的某些非必要规定。特别重要的是，委员会在其筹备工作期间，包括在专家层级上进行适当的咨询，且应根据 2016 年 4 月 13 日《改善的立法机构间协议》所规定的原则（[1]）进行这些咨询。特别是，为确保平等参与制订授权法案，欧洲议会和理事会将与成员国专家同时收到所有文件，并且其专家可系统地参加委员会专家组会议，以讨论授权法案的制订。

(91) 为确保执行本法规的条件一致，应向委员会授予执行权力。应根据欧洲议会和理事会第 182/2011 号法规（[2]）行使这些权力。

（[1]）OJ L 123, 12.5.2016, p.1。

（[2]） 欧洲议会和理事会 2011 年 2 月 16 日签发的欧盟第 182/2011 号法规，其中规定行使这些权力，规定成员国管制委员会行使其执行权力机制的规则和一般原则（ OJ L55, 28.2.2011, p. 13）。

(92) 实施细则应借助咨询程序，其中规定了制造商安全与性能总结的数据要素形式，并建立了表述以及自由销售证书模式的形式与表述，因为实施细则具有程序性，并且不会直接对欧盟层级的卫生与安全产生影响。

(93) 若存在紧急理由，即涉及到欧盟领土扩张，而相关国家豁免适当符合性评估流程，则委员会应采取立即适用的实施细则。

(94) 为使其能够任命签发机构以及欧盟参考实验室，应在委员会上授予其实施权限委员会。

(95) 为使经济运营商，特别是中小型企业、指定机构、成员国和委员会能够适应本法规引入的变化并确保其适当的应用，适当的做法是为这种适应和后期的组织安排提供充分的过渡期。但应当尽快实施法规中直接影响成员国和委员会的特定部分。特别重要的是，在本法规生效之日，根据新的要求指定足够数量的公告机构，以避免市场上器械的任何短缺。尽管如此，在法规生效日期前，有必要根据本法规要求任命一个公告机构，但不得影响这些公告机构按照第 98/79/EC 号指令任命的有效性，并且不影响其按照该指令继续签发有效证书的权限，直至本法规生效。

(96) 为确保顺利过渡至器械和证书注册的新规定，按照本法规，向在欧盟层级别设置的电子系统提交相关信息的义务（若已根据计划开发了相应的 IT 系统）应当在本法规适用日期后的 18 个月内完全有效。 在此过渡期内， 第 98/79/EC 号指令的某些条款应继续有效。但根据本法规在欧盟层级设立的相关电子系统中注册的经济运营商和指定机构应视为符合成员国根据规定所采取的注册要求，以避免多次注册。

(97) 为使 UDI 系统顺利引入， 将 UDI 载体加在器械标签上义务的生效时机还应当在本法规生效日期之后一年至五年之间完成，具体取决于相关器械的类别。

(98) 应废除第 98/79/EC 号指令，以确保只有一套规则适用于体外诊断医疗器械投放市场及本法规所涉及相关问题。制造商依然有义务为其投放市场的器械提供相关文件，而制造商和成员国依然有义务按照该指令开展已投放市场器械的监管活动。虽然应当由成员国决定如何组织监管活动，但建议成员国使用与报告依照本法规投放市场之器械相同的工具来报告使用依照该指令投放市场的器械。但该指令通过的第 2010/227/EU 号决议以及理事会第 90/385/EEC （[1]）及 93/42/EEC （[2]）号指令应于 Eudamed 完全生效之日起废除。

(99) 本法规的要求应适用于自本法规生效之日起投放市场或投入使用的所有器械。但为提供平稳过渡，应能够允许器械自该日期起的有限期限内，根据第 98/79/EC 号指令颁发的有效证书投放市场或投入使用。

(100) 欧洲数据保护主管根据欧洲委员会第 45/2001 号法规第 28（2）条发表了意见（[3]）。

（[1]） 委员会于 1990 年 6 月 20 日签发的关于有源可植入医疗器械成员国相似法案的第 90/385/EEC 号指令（OJ L 189, 20.7.1990, p.17）

（[2]） 委员会于 1993 年 6 月 14 日签发的关于医疗器械第 93/42/EEC 号指令（ OJ L169, 12.7.1993, p. 1）

（[3]） OJ C358, 7.12.2013, p.10.

(101) 出于本法规的目标，即确保医疗器械境内市场的顺利运转并确保体外诊断医疗器械的高质量和安全性，因此若患者、使用者及其他人员的卫生与安全得到高水平的保护，无法由成员国充分实现，且由于规模和效果，可更好地在欧盟层级中实现时，欧盟可根据《欧盟条约》第 5 条规定的辅助性原则采取措施。按照该条款中规定的比例原则，本法规将不会超过实现该目标所需范围。

已经通过本法规：

第 I 章

序文条款

第 1 节范围及定义

第 1 条

主题与范围

1. 本法规规定了在欧盟市场上投放、在市场上提供或投入使用的为人类使用器械及其附件的规则。 本法规也适用于在欧盟进行的体外诊断医疗器械及其附件的性能研究。

2. 就本法规而言，体外诊断医疗器械及其附件在下文中将称为“ 器械 ” 。

3. 本法规不适用于：

(a) 一般实验室使用的产品或仅限研究使用的产品，除非这些产品（鉴于其特性）由其制造商声称专门用于体外诊断检查；

(b) 侵入性取样器械或为获取样本直接用于人体的器械；

(c) 国际 有证参考物质 ；

(d) 用于外部质量评估方案的材料。

4. 投放在市场上或投入使用的作为欧盟第 2017/745 号法规第 2 条第 1 点所定义的医疗器械及组成的一部分应按该法规管理。本法规的要求应适用于体外诊断医疗器械组成部件。

5. 本法规属于第 2014/30/EU 号指令第 2（3）条欧盟特别立法所监管的范围。

6. 受欧洲议会和理事会第 2006/42/EC 号（[1]）指令第 2 条第 2 段第（ a）点所管辖的机械，在存在该法令所述的相关危险的情况下， 应同样满足该指令附录 I 中规定的基本卫生与安全要求，这些要求比本法规附录 I 第 II 章所规定的通用安全与性能要求更为具体。

7. 本法规不影响第 2013/59/Euratom 号指令的应用。

8. 若本法规未涵盖某特定类型的器械，则本法规不影响成员国覆盖限制使用该类型器械的权利。

（[1]） 欧洲议会和理事会于 2006 年 5 月 17 日签发之有关机械的第 2006/42/EC 号指令（ OJ L 157, 9.6.2006,

p.24）。

9. 本法规不影响有关卫生服务和医疗保健的组织、供应或融资的国家法律，例如要求某些器械必须依照医疗处方提供，要求只有某些卫生专业人员或卫生护理机构可分发或使用某些器械，或者要求其使用必须伴随特定的专业咨询。

10. 在欧盟及其成员国境内，本法规不得损害有关获得官方文件的公共途径以及新闻报道和其他媒体的言论自由的国家法律，特别是《欧盟基本权利宪章》第 11 条赋予的基本权利。

第 2 条

定义

就本法规而言，应适用以下定义：

(1) “ 医疗器械 ” 是指欧盟第 2017/745 号法规第 2 条第（ 1）点中定义的 “ 医疗器械 ” 。

(2) “ 体外诊断医疗器械 ” 是指任何医疗器械包括试剂、试剂产品、校准品、质控品、试剂盒、仪器、器具、成件设备、软件或系统，无论是单独使用还是组合使用，其制造目的用于体外检测来自人体的血液和组织样本，仅用于或主要用于提供以下一类或几类信息：

(a) 关于生理或病理过程或状态；

(b) 关于先天性身体或精神损伤；

(c) 关于医学病症或疾病的倾向；

(d) 确定与潜在接受者的安全性和相容性；

(e) 预测治疗效果或反应；

(f) 定义或监测治疗措施。

样本容器应归为体外诊断医疗器械；

(3) “ 样本容器 ” 是指其制造商旨在专门用于收集和保存来自人体的样本以用于体外诊断，无论是否为真空型。

(4) “ 体外诊断医疗器械附件 ” 是指虽然不是体外诊断医疗器械，但制造商旨在与一个或多个特定的体外诊断医疗器械一起使用以使其实现预期用途或根据其预期用途专门和直接地辅助体外诊断医疗器械实现其医疗功能。

(5) “ 自测器械 ” 是指由非专业人员使用的任何器械，包括用于通过社会信息服务向非专业人员提供的测试服务的器械；

(6) “ 床旁检测器械 ” 是指非自测器械，但旨在由专业医护人员在实验室环境外，通常靠近患者或在患者旁边进行测试的任何器械；

(7) “ 伴随诊断 ” 是指对于相应药品的安全和有效使用而言必不可少的器械，以便：

(a) 在治疗之前和 /或治疗期间识别最可能受益于相应药品的患者；

(b) 在治疗之前和 /或治疗期间识别可能由于使用相应药品治疗而导致严重不良反应风险增加的患者；

(8) “ 通用器械组 ” 是指具有相同或类似预期目的或技术共同性的一组器械，允许其在

不反映特性的情况下按照通用方式对其进行分类；

(9) “ 一次性使用器械 ” 是指用于一次性操作的器械；

(10) “ 虚假器械 ” 是对指其特性和 /或来源和 /或 CE 标识证书与 CE 认证相关文件进行了错误的陈述的器械。此定义不适用因无意导致的错误，并且不涉及知识产权的侵犯。

(11) “ 试剂盒 ” 是指包装在一起并且旨在用于或部分用于进行特定的体外诊断测试；

(12) “ 预期用途 ” 是指根据制造商提供的数据在产品标签上、使用说明书中、市场推广或销售材料或声明中写明的用途，并且是制造商通过性能评估确定的；

(13) “ 标签 ” 是指出现在器械本身，或单只包装上或多个器械包装上的编写、印刷或以图形表示的信息；

(14) “ 说明书 ” 是指由制造商提供，向器械使用者介绍该产品的预期用途、正确使用方法和注意事项等的材料。

(15) “ 唯一器械标识 ” （UDI ）是指通过国际认可的器械标识和编码标准创建的一系列数字或字母数字符号，可用来识别市场上的特定器械；

(16) “ 风险 ” 是指伤害发生概率和其伤害严重性的组合。

(17) “ 效益 -风险确定 ” 是指器械在根据预期用途使用时，对可能产生的所有效益和风险进行全面评估分析；

(18) “ 兼容性 ” 是当根据其预期用途与一个或多个其他器械联合使用时，器械（包括软件）的以下能力：

(a) 在使用时不失去或损害其预期使用目的，和 /或

(b) 整合和 /或操作中无需修改或与适配于组合器械的任何部分，和 /或

(c) 在没有冲突 /干扰或不良反应的情况下一起使用；

(19) “ 互用性 ” 是指来自相同制造商或不同制造商的两个或多个器械（包括软件）的以下能力：

(a) 交换信息和执行指定功能已交换的信息而不改变数据内容，和 /或

(b) 相互通信，和 /或

(c) 按照预期用途运行。

(20) “ 器械销售 /供应 ” 是指在商业活动过程中向欧盟市场上进行的以医疗器械分销、消费或使用为目的（除了用于性能研究的器械之外）的任何医疗器械的供应（不论付费或免费）；

(21) “ 投放市场 ” 是指首个在欧盟市场上市的医疗器械，用于性能研究的器械除外；

(22) “ 投入使用 ” 是指器械（用于性能研究的器械除外）在欧盟市场上已经供应给最终使用者，并可按照其预期用途首次使用的阶段；

(23) “ 制造商 ” 是指制造或全面翻新器械或拥有经设计、制造或全面翻新后的器械，并以其名称或商标销售该器械的自然人或法人。

(24) “ 全部翻新 ”，基于制造商的定义，是指对已投放市场或投入使用的器械进行全面重建，或利用已使用的器械制造新器械，使其符合本法规，并赋予翻新的器械新的生

命周期；

(25) “ 授权代表 ” 是指在欧盟境内的任何自然人或法人，其收到并接受位于欧盟以外的制造商的书面授权，代表该制造商履行本法规对制造商规定的义务；

(26) “ 进口商 ” 是指将来自第三国的器械投放于欧盟市场的在欧盟境内的任何自然人或法人；

(27) “ 经销商 ” 是指负责供应链的除了制造商或进口商之外的任何自然人或法人，负责从器械上市到投入使用的整个过程；

(28) “ 经济运营商 ” 是指制造商、授权代表、进口商或经销商；

(29) “ 卫生机构 ” 是指主要目的是照顾或治疗患者或促进公众健康的组织机构；

(30) “ 使用者 ” 是指使用器械的任何医护专业人员或非专业人员；

(31) “ 非专业人员 ” 是指未在相关医护或医学学科领域接受过正规教育的个人；

(32) “ 符合性评估 ” 是指证明器械是否满足本法规中相关国家要求的过程；

(33) “ 符合性评估机构 ” 是指执行第三方符合性评估工作的机构，工作内容包括校准、测试、认证和检查；

(34) “ 公告机构 ” 是指根据本法规指定的符合性评估机构；

(35) “ CE 符合性标识 ” 或 “ CE 标识 ” 是指制造商为表明该器械符合本法规和其他适用的欧盟协调立法中对标识相关要求而使用的标识；

(36) “ 临床证据 ” 是指足够数量和质量的与该器械相关的临床数据和性能评估结果，可用来证明当按照制造商要求使用时，器械是否安全性，能否实现预期临床受益；

(37) “ 临床受益 ” 是指与器械功能，例如筛检、监测、诊断或辅助诊断，相关的积极影响或对患者管理或公共健康的积极影响；

(38) “ 分析物的科学有效性 ” 是指分析物与临床状况或生理状态的关联；

(39) “ 器械的性能 ” 是指器械实现制造商声称的预期用途的能力，包括支持预期用途的分析性能和临床性能（如适用） ；

(40) “ 分析性能 ” 是指器械正确检测或测量特定分析物的能力；

(41) “ 临床性能 ” 是指器械从处于特定的临床状况，或生理 /病理的过程或状态下的目标人群和预期使用者获得相关结果的能力；

(42) “ 性能研究 ” 是指为建立或确认器械的分析或临床性能而进行的研究；

(43) “ 性能研究计划 ” 是指说明性能研究的原理、目标、设计方法学、监测、统计考虑要素、组织和执行的文件；

(44) “ 性能评估 ” 是指对数据的评估和分析，以建立或验证器械的科学有效性、分析性能和临床性能（如适用） ；

(45) “ 性能研究器械 ” 是指制造商预期用于性能研究的器械。

预期仅用于研究目的而不用于任何医用目的器械不视为性能研究的器械；

(46) “干预性临床性能研究”是指研究结果可能影响患者管理决定和/或用于指导治疗的临床性能研究；

(47) “受试者”是指参与性能研究的个体，其样本用于性能研究的器械和/或用于对照的器械的体外检查；

(48) “研究者”是指在性能研究场地负责执行性能研究的人；

(49) “诊断特异性”是指器械识别与特定疾病或状况相关的目标标记物不存在的能力；

(50) “诊断灵敏度”是指器械确定与特定疾病或状况相关的目标标记物存在的能力；

(51) “预测值”是指研究中具有特定属性的人为阳性测试结果或不具有特定属性的人为阴性测试结果的概率；

(52) “阳性预测值”是指器械鉴别特定群体中特定属性的真阳性结果与假阳性结果的能力；

(53) “阴性预测值”是指器械鉴别特定群体中特定属性的真阴性结果与假阴性结果的能力；

(54) “似然比”是指在具有目标临床状况或生理状态的个体产生的某一特定检测结果的可能性，与不具有该临床状况或生理状态的个体产生的该检测结果的可能性比值；

(55) “校准品”是指在器械的校准中使用的测量基准材料；

(56) “质控品”是指制造商用于验证器械性能特征的物质、材料或物品；

(57) “申办方”是指负责启动、管理性能研究和设立性能研究融资的任何个人、公司、机构或组织；

(58) “知情同意”是指将性能研究中所有影响受试者做出决定的内容告知受试者后，他或她自由和自愿地表达是否参与某一特定性能研究的意愿，或者对于未成年人和无行为能力的受试者，若要将其纳入性能研究中，必须获得法定代表的授权或允许；

(59) “伦理委员会”是指根据成员国的法律在该成员国设立的有权为本法规提供意见一个独立机构，该机构应综合考虑非专业人员，特别是患者或患者组织的意见；

(60) “不良事件”是指在性能研究的背景下，发生的受试者、使用者或其他人中的任何未预期的医疗事件、不适当的患者管理决定、意外的疾病或损伤或任何不良临床症状，包括异常的实验室结果，无论是否与性能研究器械相关；

(61) “严重不良事件”是指导致以下任一状况的不良事件：

(a) 患者管理决定对正在测试的个体造成生命威胁的状况，或者导致该个体后代死亡；

(b) 死亡，

(c) 使正在测试的个体或接受了经过测试的捐献物或材料的个体的健康严重恶化，导致以下任一状况：

(i) 危及生命的疾病或损伤；

(ii) 造成身体结构或身体机能的永久损伤，

(iii) 住院或延长患者的住院时间；

(iv) 需要医疗或手术干预以防止危及生命的疾病或损伤或身体结构或机能的永久性损伤,

(v) 慢性疾病,

(d) 胎儿窘迫、胎儿死亡或先天性身体或精神损伤或先天缺陷；

(62) “ 器械缺陷 ” 是指性能研究器械的标识、质量、耐久性、可靠性、安全性或性能的任何缺陷，包括制造商提供的信息中的故障、使用错误或缺陷；

(63) “ 上市后监管 ” 是指制造商与其他经济运营商合作开展的所有活动，目的是建立并保持最新的系统化程序，以主动收集和总结从已投放市场、供应或投入使用的器械获得的经验，以确定是否需要立即采取任何必要的纠正或预防措施；

(64) “ 市场监管 ” 是指政府当局执行的活动和采取的措施，目的是检查和确保器械符合相关欧盟协调立法中规定的要求，并且不危害健康、安全或公共利益的其他任何方面；

(65) “ 召回 ” 是指收回已提供给最终使用者的器械的任何措施；

(66) “ 撤回 ” 是指阻止供应链中的器械进一步在市场上供应的任何措施；

(67) “ 事件 ” 是指市场上供应的器械特性或性能的任何故障或劣化，包括因人体工程学特性导致的使用错误、制造商提供的信息和医疗决定而导致任何缺陷以及依据器械提供的信息或结果采取或不采取行动导致的任何损害；

(68) “ 严重事件 ” 是指直接或间接导致、本可能导致或可能会导致以下任一状况的任何事件：

(a) 患者、使用者或其他人员死亡；

(b) 患者、使用者或其他人员健康状况的暂时性或永久性严重恶化；

(c) 严重的公众健康威胁；

(69) “ 严重公众健康威胁 ” 是指可能导致危及生命的风险、人员健康状况的严重恶化或严重疾病，这种疾病可能需要立即救治或可能在人群中有较高发病率或死亡率或在特定时间和地点引发意外情况；

(70) “ 纠正措施 ” 是指为消除潜在或实际的不合格或其他不良情况而采取的措施；

(71) “ 现场安全性纠正措施 ” 是指制造商出于技术或医疗原因采取的纠正措施，目的是防止或降低发生与市场上供应的器械有关的严重事件的风险；

(72) “ 现场安全通知 ” 是指制造商向使用者或客户发送的与现场安全性纠正措施相关的信息；

(73) “ 协调标准 ” 是指欧盟第 1025/2012 号法规第 2 条第（ 1）（ c）点规定的欧盟标准；

(74) “ 通用规范 ” 是指不属于标准的技术和 /或临床要求文件，这个文件提供了如何遵守器械、流程或系统相关的法律义务的方法。

第 2 节

产品监管现状与咨询

第 3 条

产品监管现状

1. 欧盟委员会收到成员国提出充分证据的请求并咨询按照欧盟第 2017/745 号法规第 103 条成立的医疗器械协调小组（MDCG）后，应通过实施细则确定特定产品或产品类别是否满足体外诊断医疗器械或体外诊断医疗器械附件的定义。这一细则的实施应按照本法规第 107（3）条中述及所述的审查规程进行。

2. 欧盟委员会也可在咨询 MDCG 之后，自行决定通过实施细则确定本条第 1 段所述的问题。这一细则的实施应按照本法规第 107（3）条中述及所述的审查规程进行。

3. 欧盟委员会应确保成员国之间共享体外诊断医疗器械、医疗器械、医药产品、人体组织和细胞、美容产品、灭菌剂、食品和其他产品（如必要）领域的专业知识，以便判定产品或产品类别恰当的监管状态。

4. 在审议涉及医药、人体组织和细胞、灭菌剂或食品的产品器械的可能监管状况时，委员会应适当咨询欧洲药品管理局（EMA）、欧洲化学品管理局和欧洲食品安全局。

第 4 条

遗传信息、咨询和知情同意

1. 在欧盟议会和理事会第 2011/24/EU 号指令（[1]）第 3 条第（a）点所指医疗保健环境下，当对个体实施基因测试时，出于诊断、提高治疗效果、预测试验或产前检查等医疗目的，各成员国应确保接受测试的人员的法定代表有提供基因测试的性质、意义和影响的相关信息。

2. 在第 1 段所规定的义务下，当基因测试显示有目前医疗技术无法治愈的病史和/或疾病的基因倾向时，各成员国应特别确保有合理的咨询通道。

3. 第 2 段不适用于接受测试的人员已确认患有的医疗状况及/或疾病的诊断，以及使用比较诊断的方法。

4. 本条款的任何规定不得妨碍成员国在国家层面上采取或维持更好保护患者、更具体或处理知情同意的措施。

第 II 章

器械的上市供应和投入使用、经济运营商的义务、CE 标识、自由流通

第 5 条

投放市场和投入使用

1. 仅当器械遵循本法规合规供应并根据其预期使用目的正确安装、维护和使用时，该器械方可投放市场或投入使用。

（1） 欧盟议会和理事会于 2011 年 3 月 9 日签发的关于患者跨境医疗权利的第 2011/24/EU 号指令（OJ L 88, 4.4.2011, p.45）。

2. 器械应满足相关的附件 I 规定的通用安全与性能要求，同时考虑到其预期使用目的。

3. 通用安全与性能要求的遵从性证明应包含符合第 56 条的性能评估。

4. 应将在卫生机构制造和使用的器械（不包括性能研究用器械）视为已投入使用。

5. 除了附录 I 中的相关通用安全与性能要求外，此法规的规定不适用于仅在欧盟卫生机构内部生产和使用的器械，前提是能够满足以下所有条件：

(a) 该器械不被转移到另一个法律实体，

(b) 在质量达标的管理体系中制造和使用器械，

(c) 卫生机构的实验室符合 EN ISO 15189 标准或适用的国家规定之要求，包括官方认证的相关国家规定；

(d) 卫生机构在其文件中证明了，市场上的等效器械无法达到目标患者群体需要的适当性能水平。

(e) 卫生机构向其主管机构提供了这些器械的使用信息，包括生产、改装和使用的理由；

(f) 卫生机构拟定了一份公之于众的声明，包含了：

(i) 制造器械的卫生机构的地址和名称；

(ii) 识别器械的详细信息；

(iii) 一份器械满足本法规附录 I 中设定的通用安全与性能要求的声明，未满足相关要求时，声明中还有相关合理理由；

(g) 根据附录 VIII 的规则将器械归为 D 类，卫生机构起草了一份文件，助于理解生产器械、生产过程、器械的设计和性能资料，包括使用目的、以及帮助主管机构确定器械是否满足本法规附录 I 中的通用安全与性能要求的各种关键详细信息。根据附录 VIII 的规则，成员国也可将此规定应用于 A、B、C 类器械；

(h) 卫生机构会采取一切必要措施，以确保所有器械均按照（g）点所述文件中的规定进行生产；且

(i) 卫生机构会审查器械的临床使用体验，并采取一切必要的纠正措施。

成员国可要求卫生机构向主管机构提供更多在其领土上生产和使用器械的相关信息。各成员国有权限制特殊型号器械的生产和使用，且应允许成员国检查卫生机构的活动。

本段不适用于按工业规模生产的器械。

6. 为确保附录 I 统一得到应用，委员会可采用实施细则，此等细则应可达到能够解决误解和实际应用上的问题的程度。应按照第 107（3）条中述及的审查规程通过这些实施细则。

第 6 条

远程销售

1. 如第 2015/1535 号指令第 1（1）条第（ b）点所规定的，通过信息社会服务提供给位于欧盟境内的自然人或法人的器械应遵循本法规的要求。

2. 在不违反国家法律对医疗专业活动所做规定的情况下，对于未上市但用于商业活动的器械，无论有偿还是无偿使用，只要是如第 2015/1535 号指令第 1（1）条第（ b）点所规定的通过资讯社会服务或其他沟通媒介直接或间接提供给位于欧盟境内的自然人或法人的诊断服务和治疗服务均应遵循本法规的要求。

3. 应主管机构要求，根据第 1 段提供器械或根据第 2 段提供服务的自然人或法人应遵守器械的相关要求，提供一份相关器械的 EC 符合性声明。

4. 如第 2015/1535 号指令第 1（1）条第 （b）点所规定， 成员国可以保护公众健康为由，要求资讯社会服务供应商停止其活动。

第 7 条

索赔

在贴标签、使用说明、提供服务、投入使用和为器械做广告时，禁止使用误导使用者或患者器械预期使用目的、安全性和性能的文字、名称、商标、图片、图形或其他类似标识，误导手法有：

(a) 虚假器械不具备的功能和性质；

(b) 制造器械有其没有的治疗或诊断功能或其他功能和性质的假象；

(c) 未通知使用者或患者以器械预期使用目的之相关风险；

(d) 符合性评估完毕后，表明器械的用途与预期使用目的不符。

第 8 条

使用协调标准

1. 符合相关协调标准或标准相关部分的器械，其附于欧盟官方公报中的参考资料应符合本法规的全部和部分要求。

   根据本法规，第一子段也应适用于经济运营商或申办方应履行的系统要求或过程要求，包括质量管理体系、风险管理、上市后监管体系、性能研究、临床证据或上市后性能追踪（ PMPF）的相关要求。

   当前法规引用的协调标准参考资料应理解为与发表在欧盟官方公报上的参考资料一致。

2. 本法规中协调标准的参考资料还包括根据欧洲药典惯例而采纳的欧洲药典专著（前提是这些专著的参考资料已发表在欧盟官方公报上） 。

第 9 条

通用规范

1. 若无协调标准或相关协调标准不充分，或有必要处理公共健康问题时，委员会可在咨询 MDCG 后通过实施细则采纳关于以下内容的通用规范（ CS）：附录 I 中的通用安全与性能要求、附录 II 和 III 中的技术文件、附录 XIII 中的性能评估和 PMPF 或附录 XIII 中的性能研究要求。应根据第 107（3）条中所述的审查程序来采纳实施细则。

2. 应假定符合第 1 段中所述的 CS 的器械符合本法规中的相关 CS 要求（全部或相关部分）。

3. 制造商应遵守第 1 段所述的 CS，除非其能证明其已采纳的方法能够确保等效的安全性和性能水平。

第 10 条

制造商的义务

1. 当将其器械投放市场或投入使用时，制造商应确保所有器械均按本法规的要求进行设计和生产。

2. 制造商应如附录 I 第 3 节所述，确立、记录、执行和维护风险管理体系。

3. 制造商应按照附录 XIII 和第 56 条的要求进行性能评估，包括 PMPF。

4. 制造商应制定并不断更新这些器械的技术文件。技术文件允许评估器械是否符合本法规的要求。技术文件应包含附录 II 和 III 中的要素。

   委员会应按照技术进展，有权根据第 108 条修订附录 II 和附录 III 采纳授权法案。

5. 若适用的符合性评估程序证明器械符合适用的要求，则器械（非性能研究用器械）制造商应根据第 17 条的要求制定欧盟符合性声明，并根据第 18 条的要求附上标有符合性标识的 CE。

6. 制造商应遵守第 24 条中所述的 UDI 系统相关义务， 以及第 26 和 28 条所述的注册义务。

7. 制造商应保存技术文件、欧盟符合性声明、适用时还有根据第 51 条颁发的相关证书的副本，包括所有修改和补充，在欧盟符合性声明中所涵盖的最后一件器械上市后，该文档应至少向主管机构开放 10 年。

   经主管机构要求，制造商应根据本文要求提供完整的技术文件或摘要。

   为使授权代表能够完成第 11（3）条中所述的任务， 在欧盟境外注册营业的制造商应

确保授权代表有永久可用的必要文档。

8. 制造商应确保采取必要流程，以使系列产品的生产符合本法规的要求。应及时充分考虑产品设计或特性的更改和协调标准或产品符合性所声明的 CS 的更改。以与风险等级和器械类型成比例的方式，器械（非性能研究用途器械）制造商应以最有效的方式确立、记录、实现、维护、不断更新和不断改善一个能确保器械符合本法规规定的质量管理体系。

质量管理体系包括制造商组织的所有处理流程、程序和器械质量的组成部分。它管理着必要的结构、职责、程序、流程和管理资源，以贯彻必要的原则和行动，以遵守本法规的规定。

质量管理体系应至少包括以下方面：

(a) 法规符合性战略，包括符合性评估流程的遵守和系统所涵盖的器械的变更管理；

(b) 确定适用的通用安全与性能要求，寻找满足这些要求的选项；

(c) 管理责任；

(d) 资源管理，包括选择和管理供应商和分包商；

(e) 附录 I 第 3 节规定的风险管理；

(f) 性能评估，根据第 56 条和附录 XIII 的规定，包括上市后的性能追踪；

(g) 产品实现规划，包括规划、设计、研发、生产和服务提供；

(h) 根据第 24（3）条为所有相关器械的 UDI 分配验证，并确保根据第 26 条提供的信息的一致性和有效性；

(i) 根据第 78 条的要求，建立、实施和维护上市后监管体系；

(j) 与主管机构、公告机构、其他经济运营商、客户和 /或其他利益相关人沟通；

(k) 警戒情况下的严重事件和现场安全纠正措施的报告流程；

(l) 纠正措施和预防措施的管理及其有效性的验证；

(m) 产品，数据分析和产品改进的监督和评估流程。

9. 器械制造商应实施并不断更新第 78 条中所述的上市后监管体系。

10. 制造商应确保器械附有附录 I 第 20 节所要求的信息，而且信息采用器械上市国（同时也是成员国）指定的欧盟官方语言编写。标签上的详情不得能拭除、容易识别并且预期使用者和患者能够清楚理解。

对于自测或床旁检测器械，根据附录 I 第 20 条所提供的信息应易懂，且为器械上市国（同时也是成员国）指定的欧盟官方语言。

11. 认为或有理由认定其投放于市场或交付使用的器械未遵照本法规的制造商，应立即采取必要纠正措施使器械符合要求，并适时撤回或召回。其应通知该器械的经销商，并适时通知授权代表和相应进口商。

若器械出现严重风险，制造商应立即通知使用医疗器械各成员国主管机构以及根据

第 51 条为器械颁发证书的公告机构，特别是未遵守要求及其采取的纠正措施。

12. 制造商应有一套如第 82 和 83 条所述，记录和报告意外事件和现场安全的纠正措施系统。

13. 制造商应根据主管机构要求，由相关成员国用官方欧盟语言确定，提供其一切必要信息和文档以证明器械符合要求。如制造商有其注册的营业地点，所在成员国主管机构可要求制造商免费提供器械样品，如不可行，则授予其器械访问权。制造商应与主管机构合作，按其要求，采取纠正措施以消除风险，如不可行，则减轻其已投放市场或投入使用的器械所导致的风险。

如制造商合作失败或提供的信息和文档不完整或不正确，则主管机构为确保保护公众卫生和患者安全，将采取一切必要措施，以禁止或限制在国内市场购得该器械，从该市场撤回或召回器械直至制造商与主管机构合作，或提供完整且正确的信息。

若主管机构认为或有理由认定器械已造成损害，应当根据要求，协助提供有关第一子段的信息和文档，在不影响数据保护规则，除非披露凌驾性公众利益，且不影响知识产权保护的前提下，给潜在受伤患者或使用者、患者或使用者的所有权继承人、受伤患者或使用者的医疗保险公司或经受伤患者，或使用者影响的其他第三方。若第一子段所述的信息和文件披露一般是按法律程序进行，则主管机构无须遵守在第 3 子段中规定的义务。

14. 如制造商将其器械交由其他法人或自然人设计或制造，则按照第 27（1）条，其法人或自然人的身份信息将成为待提交信息的一部分。

15. 自然人或法人可按照适当欧盟和国家法律，要求对由缺陷器械引起损害进行赔偿。以与风险等级、器械类型和企业规模相应的方式，制造商应采取措施提供其潜在责任的足够财政保障，并根据国家法律，在不影响更多防护措施的情况下，根据第 85/374/EEC 指令关于。

第 11 条

授权代表

1. 当器械在所有成员国都没有建立制造商时，仅当制造商指定单一授权代表时，该器械方可投放于欧盟市场。

2. 委任应构成授权代表的授权书，只有在授权代表书面许可时，且至少在相同通用器械组的所有器械有效时，才有效。

3. 授权代表应执行其与制造商之间授权同意的指定任务。授权代表应根据要求向主管机构提供授权书副本。

授权书应要求且制造商应允许授权代表至少执行相关器械的以下任务：

(a) 确认欧盟符合性声明和技术文件的已拟定，且在适当时核实制造商已实施适当符合性评估流程。

(b) 保留一份可用的技术文件、欧盟符合性声明副本，如适用，保留一份包括所有修订和补充的相关证书副本，并按照第 51 条，在第 10（7）条指定时期，由主管机构签发；

(c) 遵守第 28 条规定的注册义务，并确认该制造商已遵守第 26 条规定的注册义务；

(d) 响应主管机构的要求，提供所有必要信息和文档，使用相关成员国确定的欧盟官方语言，证明器械符合要求；

(e) 向制造商转达，授权代表业务注册地成员国主管机构对于样品及获取仪器的所有要求，并确认主管机构已收到样品或器械；

(f) 配合主管机构采取任何预防或纠正措施以消除或减轻由器械导致的风险；

(g) 立即通知制造商来自医护专业人员、患者和使用者与有关指定器械可疑事件的投诉和举报；

(h) 如制造商违反本法规义务，则终止授权书。

4. 本条第 3 段所述的授权书不得授权第 10 条（1）、（2）、（3）、（4）、（5）、（6）、（8）、（9）、（10）和（ 11）所规定制造商的义务授权。

5 在不影响本条第 4 段的情况下，当所有成员国的制造商都未确立，且未遵守第 10 条规定义务时，授权代表应与制造商按照共同或各自的相同基准，为缺陷器械承担法律责任。

6. 根据第 3 段第（ h）点所述的理由终止授权书的授权代表应立即通知确定其为授权代表的成员国的主管机构，如适用，通知参与因本终止授权器械符合要求评定的公告机构。

7. 在制造商有其注册经营地的成员国内，本法规对主管机构的参考应理解为，在有其注册经营地的制造商，根据第一段指定对授权代表的成员国内，对主管机构的参考。

第 12 条

授权代表变更

授权代表变更的详细安排应在制造商之间的协议中明确定义，本协议应对即将卸任与新任的授权代表可行。本协议应至少解决以下几个方面：

(a) 即将卸任的授权代表，其授权的终止日期为新任授权代表的授权开始日期；

(b) 直至授权代表将卸任的日期可在由制造商提供的，包括任何宣传材料的信息上注明；

(c) 文件传输，包括机密性方面和产权；

(d) 授权结束后，将即将卸任授权代表的义务转交给制造商或新任授权代表，来自医护专业人员、患者和使用者，与由授权代表指定器械相关可疑事件的投诉和举报。

第 13 条

进口商的一般义务

1. 仅当器械遵照本法规时，进口商才能将器械投入欧盟市场。

2. 为将器械投放市场，进口商应核实以下事项：

(a) 该器械已作 CE 标识，且器械的欧盟符合性声明已起草完毕；

(b) 制造商已确定，按照第 11 条，授权代表由制造商来指定；

(c) 该器械按照本法规和要求的使用说明进行标记；

(d) 即，如适用，按照第 24 条， UDI 由制造商指定；

若进口商认为或有理由相信器械不符合本法规要求，则在器械符合要求前不得将其投放市场，并应通知制造商及其授权代表。若进口商认为或有理由相信该器械出现严重的风险，或为虚假器械，其还应通知进口商登记成立的成员国的主管机构。

3. 进口商应注明其名称、注册商号或注册商标，及其可联系的经营注册地址，和其可建立于器械或者器械附随包装或文档的位置。其应确保任何附加标签，且不得掩盖制造商提供标签上的任何信息。

4. 进口商应核实该器械具有按照第 26 条的电子系统注册。进口商应按照第 28 条，将其详细资料添加注册。

5. 进口商应确保器械在其责任下、 储存或运输条件不损害其遵守附录 I 所列的通用安全与性能要求，且如适用应遵守制造商所列条件。

6. 进口商应保存不合格器械和召回及撤回投诉记录，并提供制造商、授权代表和经销商以其所要求的所有信息，以便于其调查投诉。

7. 如进口商认为或有理由相信其投放到市场上的器械不符合本法规，应立即通知制造商及其授权代表。进口商应与制造商、其授权代表及主管机构合作，确保已采取必要的纠正措施，如使器械符合要求，撤回器械或召回器械。当器械出现严重风险，其也应立即通知已有这些器械的各成员国主管机构，如适用，公告机构应按照第 51 条颁发证书，至于有问题的器械，应给出细节，特别是未遵守要求及其采取的纠正措施。

8. 如进口商收到来自医护专业人员、患者和使用者，关于投放于市场器械的相关可疑事件的投诉和举报，应立即通知制造商及其授权代表。

9. 进口商应在第 10（7）条所指期间，保留欧盟符合性声明副本，如适用，保留根据第 51 条发出的副本，包括所有校正和补充的相关证书副本。

10. 进口商应与主管机构合作，按后者要求，采取任何行动以消除或，降低其投放于市场器械导致的风险。进口商所在成员国按主管机构要求，若进口商有其经营注册地，应提供免费器械样品或，如不可行，则应允许访问该器械。

第 14 条

经销商的一般义务

1. 在其活动范围内，使器械上市时，经销商应适当谨慎地执行适用的要求。

2. 使器械可于市场购得前，经销商应核实是否满足所有以下要求：

(a) 该器械已有 CE 标识，且器械的欧盟符合性声明已起草完毕；

(b) 该器械与制造商按照第 10(10)条提供的信息相符；

(c) 关于进口器械，进口商已遵守第 13（3）条列出的要求；

(d) 如适用，制造商已指定 UDI 。

为满足第一子段第（ a)、（b）和（ d）点所述要求，经销商可申请由抽样获得的代表器械。

如经销商认为或有理由相信器械不符合本法规的要求，在器械符合要求之前不可将器械推向市场，同时应通知制造商及（如适用）其授权代表与进口商。如经销商认为或有理由相信该器械出现严重的风险，或为虚假器械，其还应通知其所在成员国的主管机构。

3. 经销商应确保器械在其责任范围内时，储存或运输条件应符合制造商规定。

4. 如经销商认为或有理由相信，投放市场的器械不符合本法规，应立即通知制造商和（如适用）制造商授权代表和进口商。经销商应与制造商、主管机构和（如适用）制造商授权代表与进口商合作，以确保已采取必要的纠正措施，以使器械符合要求、撤回器械或召回器械。如经销商认为或有理由相信该器械出现严重风险，其也应立即通知器械销售所在成员国的主管机构，给出细节，特别是未遵守要求及其采取的纠正措施。

5. 如经销商收到来自医护专业人员、患者和使用者，关于可购得器械相关可疑事件的投诉和举报，应立即将此信息通知制造商和（如适用）制造商授权代表和进口商。其应保存不合格器械和召回及撤回投诉记录，并通知制造商和（如适用）授权代表及经销商此种监控，并按其要求向其提供所有信息。

6. 应主管机构请求，经销商应自主提供足以证明器械符合性的所有资料和文件。

当制造商或（如适用）授权代表针对上述器械提供所需信息时，应视为经销商已履行第一子段所述之义务。经销商应主管机构要求，配合主管机构，采取任何行动以消除其在市场上所提供器械带来的风险。经销商应主管机构要求提供免费的器械样品，或者若无法提供免费样品，则授予对器械的访问权。

第 15 条

负责法规符合性的人员职责

1. 制造商应在其组织内至少拥有一名在体外诊断医疗器械领域具有必要专业知识的人员负责法规符合性。必要的专业知识应表现为以下任一一种资格：

(a) 在完成有关成员国确认为同等学历的法律、医学、药学、工程或其他相关科学学科大学学历或学习课程后颁发的文凭、证书或其他正式资格证书，以及在体外诊断医疗器械相关法规事务或质量管理体系方面具有至少一年专业经验；

(b) 在体外诊断医疗器械法规事务或质量管理体系方面具有四年的专业经验。

2. 在委员会第 2003/361/EC 号建议（[1]）含义范围内的微型和小型企业在其组织内无需有负责法规符合性的人员，但应有可永久且持续听其调遣的人员。

3. 负责法规符合性的人员至少应负责确保：

(a) 根据制造这些器械的质量管理体系，在器械上市之前适当检查器械符合性；

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1 2003 年 5 月 6 日关于微型、小型和中型企业的委员会建议（OJ L 124, 20.5.2003, p.36）。

(b) 制定技术文件和欧盟符合性声明书并保持其最新版本；

(c) 遵守第 10(9)条规定的上市后监管义务；

(d) 履行第 82 至 86 条规定的报告义务；

(e) 在打算将用于性能研究的器械用于干预性临床性能研究或涉及受试者风险的其他性能研究的情况下，发布附录 XIV 第 4.1 节所述的声明；

4. 若根据第 1、2 和 3 段规定，多人共同负责法规符合性，则其各自的责任领域应以书面形式规定。

5. 在制造商组织内负责法规符合性的人员，不论其是否属于该组织的雇员，在履行其职责方面不得有任何不利。

6. 授权代表应至少有一名可永久且持续听其调遣的负责法规符合性的人员，其在欧盟境内的体外诊断医疗器械监管要求方面拥有必要的专业知识。必要的专业知识应表现为以下任一一种资格：

(a) 在完成有关成员国确认为同等学历的法律、医学、药学、工程或其他相关科学学科大学学历或学习课程后颁发的文凭、证书或其他正式资格证书，以及在体外医疗器械相关监管事务或质量管理体系方面具有至少一年专业经验；

(b) 在体外诊断医疗器械监管事务或质量管理体系方面具有四年的专业经验。

第 16 条

制造商的义务适用于进口商、经销商或其他人的情况

1. 经销商、进口商或其他自然人或法人若做出以下任何行为，则应承担制造商相应义务：

(a) 在市场上提供以其名字、注册商标名称或注册商标命名的器械，除非经销商或进口商与标签上标明的制造商签订协议，仅由制造商承担本法规对制造商规定的要求；

(b) 变更已投放市场或投入使用的器械的预期用途；

(c) 更改已投放市场或投入使用的器械，若按照适用要求影响符合性。

第一子段不适用于为个别患者组装或改装已上市器械（且未更改器械之预期用途）的任何人员（此等人员并不视为第 2 条第（ 23）点所定义之制造商） 。

2. 对于第 1 段（c）点而言，以下情况不得视为器械更改可能影响其适用要求的合规情况：

(a) 提供附录 I 第 20 节规定之已上市器械的制造商信息，以及用于在相关成员国推销器械所需的进一步信息，包括此等信息的译文；

(b) 对已上市器械的外包装改变，若为在相关成员国推销该器械而有必要重新包装且若重新包装不会影响器械原始状态，包括改变包装尺寸。 对于无菌上市的器械，若应维持无菌状态的包装因重新包装而打开、破损或者受到其他负面影响，则应推定该器械的原始状态受到不利影响。

3. 任何进行第 2 段（a）及（b）点活动的经销商或进口商应在器械上或者（如不可行）在其包装上或器械所附的文件上标明进行活动的名称、注册商标名或者注册商标、注册营业地址及有效联系地址，以方便确认其位置。

经销商和进口商应确保具有一套质量管理体系，其中的流程可适当保证信息译文准确且及时更新，该体系还能够保证以保持器械原始状态不变的方式和条件进行第 2 段（a）和（b）点中的活动以及保证重新包装的器械包装应没有缺陷，质量良好且整洁。质量管理体系应特别涵盖以下流程：确保经销商或进口商了解任何有关制造商为反馈安全问题或使器械符合本法规规定对有关讨论器械所采取的任何纠正行动。

4. 至少在对所提供器械重贴标签或重新包装的 28 日之前，市场上开展第 2 段（a）和（b）点中所述活动的经销商或进口商应通知制造商和计划供应器械的成员国的主管机构，其准备销售重新贴标签或重新包装的器械，并根据要求应向制造商和主管机构提供一个重贴标签或重新包装器械的样品或实体模型，其中包含翻译版本的标签和使用说明。在同一 28 日期限内，经销商或进口商应向主管机构提交一份证书。该证书由公告机构颁发给用于进行第 2 段（a）和（b）点所述活动的器械，以用于证明经销商或进口商的质量管理体系符合在第 3 段中规定的要求。

第 17 条

欧盟符合性声明

1. 欧盟符合性声明应说明已履行本法规规定要求。制造商应当持续对其进行更新欧盟符合性声明。这一欧盟符合性声明最低限度内容列于附录 IV。应将其翻译成欧盟官方语言或者器械销售所在成员国所要求的语言。

2. 就本法规未涵盖的相关问题，若器械需遵守其他欧盟立法机构要求（该立法机构要求制造商发布一份证实已履行该立法机构所规定要求的欧盟符合性声明书），只需要起草有关所有欧盟法案均适用该器械的单独符合性声明书。声明书中包含所有标识声明书相关欧盟立法机构的必要信息。

3. 通过起草欧盟符合性声明书，制造商应承担遵守本法规和适用于器械的所有其他欧盟立法机构要求的责任。

4. 委员会应有权按照第 108 条规定通过授权法案，基于技术进步来修订附录 V 规定的欧盟符合性声明的最低限度内容。

第 18 条

CE 符合性标识

1. 除了用于性能研究的器械之外，视为符合本法规要求的器械应加贴如附录 V 中所示的合规 CE 标识。

2. CE 标识应遵守欧洲委员会第 765/2008 号法规第 30 条要求所载的一般原则。

3. 标签应明显、清晰和不可磨灭地添加在器械或其无菌包装上。考虑到器械性质，无

法或不适合将标签或添加到器械上时，应将 CE 标识添加在包装上。 CE 标识也应出现在使用说明书中和销售包装上。

4. 应在器械上市前添加 CE 标识。其可能跟随在任何一个表示特殊危险或用途的象形图或任何其他标记后面。

5. 如适用， CE 标识应紧跟在负责进行列于第 48 条的符合性评估流程的公告机构标识号后面。也应在任何宣传材料（其中所述器械满足 CE 标识的要求）中说明标识号。

6. 若器械需遵守其他欧盟立法机构要求添加 CE 标识的规定， 则 CE 标识还应表明该器械符合其他立法机构要求。

第 19 条

用于特殊用途的器械

1. 若对供应给实验室或其他机构进行性能研究的器械满足第 57 至 76 条中规定的条件，以及按照第 77 条通过的实施细则中规定的条件， 则成员国不得为此等器械制造任何障碍。

2. 第 1 段中所述的器械（在第 70 条中所述的器械除外）不得加贴 CE 标识。

3. 在交易会、展览会、展示会或类似活动上，成员国不得制造任何障碍，表明器械不符合本法规要求，但前提是在器械上清楚标明该器械仅用于展示或演示目的且在未按照本法规规定制造之前不可投入使用的明显记号标识。

第 20 条

部件和组件

1. 任何在市场上提供专门用于取代相同或类似的有缺陷或磨损器械组成部分或组件的物项，以维持或恢复器械功能的自然人或法人，应在不改变器械性能或安全特征或其预期用途情况下，保证该物项对器械安全与性能没有不利影响。支持证据应可供成员国主管机构随时获取。

2. 专门用于替代器械部件或组件和显著改变器械性能或安全特征或预期用途的物项，应视为器械且应满足本法规规定的要求。

第 21 条

自由流通

除非本法规另有规定，否则成员国不得拒绝、禁止或限制在其领土内上市或使用符合本法规要求的器械。

第 III 章

器械的标识和可追溯性、器械和经济运营商的登记、安全和临床性能总结、欧洲医疗器械数据库

第 22 条

供应链中标识

1. 经销商和进口商应与制造商或授权代表合作，以实现器械适当水平的可追溯性。
2. 在第 10（7）条所述期限，经济运营商应能够向主管机构确定以下内容：
   (a) 其直接提供器械的任何经济运营商；
   (b) 直接向其提供器械的任何经济运营商；
   (c) 其直接提供器械的任何卫生机构或卫生保健专业人员。

第 23 条

医疗器械的命名

为协助根据欧盟第 2017/745 号法规第 33 条所述的欧洲医疗器械数据库（Eudamed）的运作，委员会应确保国际公认的医疗器械命名应按照本法规要求，免费提供给需要使用命名的制造商和其他自然人或法人。委员会还应努力确保在合理可行的情况下免费向其他利益相关方提供这一命名。

第 24 条

唯一器械标识系统

1. 除用于性能研究的器械外，附录 VI 第 C 部分中说明的唯一器械标识系统（UDI 系统）应能对器械进行标识并辅助医疗器械进行溯源管理，此外还应包括以下内容：
   (a) UDI 的产生包括以下几点：
      (i) 特定于某一制造商和某种器械的 UDI 器械标识（UDI- DI），提供附录 VI 第 B 部分所述信息访问途径；
      (ii) UDI 生产标识（UDI- PI），用于标识器械生产单品包装以及附录 VI 第 C 部分中规定的销售包装器械（若适用）；
   (b) 将 UDI 应用于器械的标签或其包装上；
   (c) 经济运营商、医疗机构及以医护人员分别根据第 8 和 9 段的规定相应要求保存 UDI；
   (d) 根据欧盟第 2017/745 号法规第 28 条建立唯一器械标识电子系统（UDI 数据库）。
2. 委员会应通过实施细则指定一个或多个机构，该机构根据本法规规定进行 UDI 工作系统运行及日常工作（“签发机构”）。该等机构应满足以下所有标准：
   (a) 实体是应具有法人资格的组织；
   (b) 其 UDI 工作系统足以根据本法规要求，在从分销到使用的整个过程中对器械进行标识；
   (c) 其 UDI 工作系统应符合相关国际标准；
   (d) 该机构可根据一组预定的和透明的条款和条件，将 UDI 工作系统的访问权限提供给所有相关使用者；
   (e) 该机构需做出以下几点承诺：
      (i) 在得到委任后，应能够运作其 UDI 工作系统至少 10 年；
      (ii) 提供给委员会和各成员国使用，并应要求，提供 UDI 工作系统的相关信息；
      (iii) 符合相应的工作标准及相应条款要求。

委任签发机构时，委员会应努力确保无论签发机构使用何种系统，UDI 编码载体作

为附件 VI 第 C 部分均能通过通用的方式读取，为经济运营商、医疗卫生机构和医疗保健专业人士减少财务和行政负担。

3. 在将器械（性能研究器械除外）投放于市场之前，制造商应向器械和（如适用）所有较高包装等级医疗器械进行 UDI 编码，该编码应符合委员会根据第 2 段委任的签发机构颁布之规定。

制造商将器械（性能研究用器械除外）投放市场之前，须确保附录 V 第 B 部分中所列的与器械有关的资料准确提交且上传至第 25 条所述的 UDI 数据库。

4. UDI 载体应添加在器械标签和所有较高等级包装的器械上。较高包等级装的器械不得理解为包括海运集装箱。

5. 根据第 82 条规定，UDI 应能用于报告严重不良事件及现场安全纠正措施。

6. 第 17 条所述的欧盟符合性声明应说明该器械的基本 UDI - DI（定义见附录 VI 第 C 部分）。

7. 制造商应及时更新所有适用的已指定 UDI 的清单，并作为附录 II 中所述技术文件的一部分。

8. 若器械属于第 11 段(a)中所述方法确定的器械类别或器械组别，经济运营商应优先通过电子方式存放和保管其已提供或获取的器械 UDI 。

9. 成员国应鼓励，并可要求医疗卫生机构优先通过电子手段存放并保管提供给其器械的 UDI 。

成员国应鼓励，并可要求健康护理人员优先通过电子手段存放并保管提供给其器械的 UDI 。

10. 委员会应有权根据第 108 条通过以下授权法案：

(a) 从技术进步的角度修订附录 VI 第 B 部分列表信息；及

(b) 按照唯一器械标识领域的国际发展及技术进步修订附录 VI 。

11. 委员会可通过实施细则来规定 UDI 系统的详细安排及程序，以此来确保适用以下几个方面：

(a) 判定用于第 8 段所规定义务适用的器械类别或器械组别。

(b) 指定特定器械或器械组别的 UDI - PI 中所包含的数据；

应按照第 107（3）条中所述的审核方式来通过第一子段所述的实施细则。

12. 采用第 11 段所述措施时，委员会应考虑以下所有事项：

(a) 第 102 和 103 条中分别所述的保密性和数据保护；

(b) 基于风险的方法；

(c) 成本效益的措施；

(d) 以国际水准开发 UDI 系统；

(e) 避免 UDI 系统重复的需求；

(f) 成员国对医疗系统的需要，及在尽可能的情况下，与利益相关方使用的其他医疗器械的识别系统的兼容性。

第 25 条

UDI 数据库

在咨询 MDCG 后，委员会应根据欧盟第 2017/745 号法规第 8 条设立的条件及详细安排设立并管理 UDI 数据库。

第 26 条

器械注册

1. 器械投放市场之前，制造商应按第 24（2）条所述的签发机构相关规则，为器械指定一个附录 V 第 C 部分要求的“基本 UDI - DI ”，并将其连同附件 VI 第 B 部分中所述的器械相关核心数据要素提交至 UDI 数据库。

2. 对于受第 48（3）条和 48（4）条、第 48（7）条第二子项、第 48（8）条以及第 48（9）第二子项所述的符合性评估限制的器械，在相关制造商向公告机构申请该评估流程前，应指定本条第 1 段所指基本 UDI - DI 。

   对于第一子段所述的器械，公告机构应引用根据附录 XII 第 4 节第（a）点签发的证书的基本 UDI - DI ，并在 Eudamed 中确认附录 VI 第 A 部分第 2.2 节中所述资料。 相关证书签发后，在器械投放市场之前制造商应将基本 UDI - DI 连同附件 VI 第 B 部分中所述的器械相关其他核心数据要素提交至 UDI 数据库。

3. 将器械投放市场之前，制造商应向 Eudamed 录入或（若已存在）验证附录 VI 第 A 部分第 2 节（除第 2.2 节外）所述的资料，并应及时更新资料。

第 27 条

经济运营商注册电子系统

1. 在咨询 MDCG 后，委员会应当建立并管理电子系统以创建第 28（2）条所述的单一注册号。与制造商、授权代及进口商（如适用）识别相关的重要信息的收集并整理。

   有关经济运营商提供给该电子系统的资料详情详见附录 VI 第 A 部分第 1 节。

2. 成员国可维持或引用有关其领土范围内允许使用的器械的经销商注册的国家规定。

3. 器械投放市场两周内，进口商应核实制造商或授权代表已将第 1 段中所述的资料提交至电子系统中。

   若第 1 段资料未上传或不正确，在适用的情况下，进口商应通知相关授权代表或制造商。进口商应将其详细资料添加到相关条目。

第 28 条

制造商、授权代表和进口商的注册

1. 在器械投放市场前，制造商、授权代表和进口商为完成登记，应当向第 30 条所述的电子系统提交附录 VI 第 A 部分第 1 节所述资料。 如符合性评估流程需公告机构按照第 48 条参与，应在向公告机构申请前向电子系统提交附录 VI 第 A 部分第 1 节所述的资料。

2. 在根据第 1 段要求输入的数据经过核实后，主管机构应从第 27 条所述的电子系统取得单一注册号 ('SRN') 并签发给制造商、授权代表或进口商。

3. 制造商向公告机构申请符合性认证及访问 Eudamed（为履行第 26 条下的义务）时需

要用到 SRN。

4. 若有关本条第 1 段所述的资料于一周内发生任何变动，经济运营商应更新第 27 条中所述的电子系统中的数据。

5. 在按照第 1 段所述的要求提交资料后一年内及此后的每两年，经济运营商应确认数据的准确性。在六个月到期日内未满足此要求的情况下，任何成员国可于其领土范围内采取适当的纠正措施，直至该等经济运营商遵守相关义务。

6. 在不影响经济运营商对数据的责任的情况下，主管机构应核实附录 VI 第 A 部分第 1 条中所述的已确认的数据。

7. 第 27 条所述的电子系统中，按照本条第 1 段输入的数据应向公众开放。

8. 根据第 104 条，主管机构可利用这些数据来向制造商、授权代表或进口商收取一笔费用。

第 29 条

安全性和性能总结

1. 对于 C 类和 D 类器械，除性能研究器械外，制造商应制定安全性和性能总结。

该安全性和性能总结对预期使用者及（如相关）患者应足够清晰，并应通过 Eudamed 向公众开放。

依据第 48 条，该安全性和性能总结的草案应当是包含在提交给公告机构的符合性评估的文件的一部分，并由该机构来确认。确认后，公告机构应将该总结上传到 Eudamed。制造商应在标签或使用说明所述总结可获得的地址。

2. 安全性和性能总结应至少包括以下方面：

(a) 器械和制造商标识，包括基本 UDI - DI 和（若已经签发） SRN；

(b) 该器械的预期用途以及任何适应症、禁忌症和适用人群；

(c) 该器械的说明，包括前一代或变体（如存在）的参考文件，和差异说明，以及（如相关）附件、其他器械和产品等与该器械配套使用物品的说明；

(d) 协调标准和适用的 CS 的参考文件；

(e) 附录 XIII 所述的性能评估总结，和有关 PMPF 的相关资料；

(f) 赋值的计量学溯源性；

(g) 为使用者提供的建议简况和培训；

(h) 有关任何剩余风险和任何不良影响、警戒和预防措施的信息。

3. 委员会可通过实施细则，将纳入安全性和性能总结的数据进行公示。应按照第 107（2）条中规定的审查规程实施细则。

第 30 条

欧洲医疗器械数据库

1. 委员会咨询 MDCG 后，应按照欧盟第 2017/745 号法规的第 33 及 34 条设立的条件和详细安排制定、维持及管理欧洲医疗器械数据库 (Eudamed)。

2. Eudamed 应包括以下电子系统：

(a) 第 26 条所述的器械注册电子系统；

(b) 第 25 条所述的 UDI 数据库；

(c) 第 27 条所述的经济运营商备案登记电子系统；

(d) 第 52 条所述的公告机构和证书电子系统；

(e) 第 69 条所述的性能研究电子系统,

(f) 第 87 条所述的警戒和上市后监管电子系统；

(g) 第 95 条所述的市场监管电子系统。

第 IV 章
公告机构

第 31 条

负责公告机构的主管机构

1. 成员国如计划指定符合性评估机构为公告机构，或已指定一家公告机构来根据本法规开展符合性评估活动，则应任命一个主管机构（ “负责公告机构的主管机构” ）。该主管机构由多个单独实体依照国家法律组建而成，负责建立和实施符合性评估机构的评估、指定和通告相关的必要流程以及对公告机构的监督管理（包括该机构的分包商和分支机构） 。

2. 负责公告机构的主管机构应当妥善建立、组织和运作，以保障其活动的客观性和公正性，并避免与符合性评估机构的任何利益冲突。

3. 负责公告机构的主管机构应当妥善组织，以保证与指定或公告相关的每一个决定均由不同于评估的其他人员做出。

4. 负责公告机构的主管机构不得参与公告机构按商业或竞争形式开展的任何活动。

5. 负责公告机构的主管机构应对其获得的信息进行保密。但可与其他成员国、委员会及其他监管机构（在需要时）交换有关信息。

6. 负责公告机构的主管机构应维持足够数量的专业人员来保障其工作正常进行。

   倘若负责公告机构的主管机构为不同于体外诊断医疗器械主管机构的机构，其须确保就相关事宜向体外诊断医疗器械的负责机构做出咨询。

7. 成员国应公开一些基本信息，包括管理符合性评估机构评估、任命和公告等方面工作的措施，以及公告机构监管方面的信息，还有对这些工作有重大影响的变化。

8. 负责公告机构的主管机构应参与第 44 条规定的同行评审活动。

第 32 条

公告机构的相关要求

1. 公告机构应当满足本规范指定的任务。其应当满足组织及基本要求、以及满足这些任务所需的对于质量管理、资源和程序的要求。公告机构特别需要满足附录 VI 的任务。

   为满足第一子段指定的要求，公告机构应（按照附录 VII 第 3.1.1 条的规定）维持充

足的行政、技术和科研人员，以及相关临床专业人员（按照附录 VII 第 3.2.4 条的规定）；如有可能，可由公告机构自行聘用。

附录 VII 第 3.2.3 及 3.2.7 条所述的人员应由公告机构自行雇佣，且不得担任外部专家或分包商。

2. 公告机构应准备并在需要时向负责该公告机构的主管机构提供所有相关文件（包括制造商文件），使其能够开展评估、指定、通告、监管及监督活动，并辅助在本章节内列出的评估活动。

3. 为确保统一应用附录 VII 所列要求，必要情况下为解决误解和实际应用上的问题，委员会需要颁布实施细则。这些实施细则应根据第 84(3) 条所述的检测程序来审批通过。

第 33 条

分支机构和分包

1. 若公告机构要把与符合性评估相关的特定任务外包，或者分派给分支机构，则应确认分包商或分支机构符合附录 VII 中规定的相应要求，并应通知负责公告机构的主管机构。

2. 分包商或分支机构如代表公告机构履行任务，则公告机构需对其所履行的任务承担全部责任。

3. 公告机构应公开其分支机构名单。

4. 在相应告知申请符合性评估的法人或自然人的前提下，符合性评估活动可分包商或由分支机构开展。

5. 在公告机构的主管机构安排下，公告机构应保留关于分包商或分支机构的资格验证及其根据本法规开展工作的所有相关文件。

第 34 条

符合性评估机构提交的委任申请

1. 符合性评估机构应向负责公告机构的主管机构提交委任申请。

2. 该申请应明确本法规中规定的符合性评估活动以及申请委任的器械类型，并由证明符合附录 VI 要求的所有证明文件提供证明。

关于组织及基本要求以及附录 VII 中第 1 节和第 2 节所规定的质量管理要求，国家委任机构根据欧洲委员会第 765/2008 号法规提交的有效任命证书和相应的评估报告，并应在第 35 条所述的评估中予以考虑。但是，申请人应提供第一子段所述的完整文件，用来证明符合这些要求。

3. 为确保负责公告机构的主管机构能够监督和查证该公告机构是否符合附录 VII 中的所有要求，该公告机构应就任何相关变化更新第 2 段中所述的文件。

第 35 条

申请评估

1. 负责公告机构的主管机构应在 30 天内确认是否完成第 34 条所述的申请，并应要求申请机构提供所有缺失的信息。一旦申请完成，负责公告机构的主管机构应将其交送给委员会。

   国家主管机构应按照自己的流程审查申请表和支持文件， 并起草一份初步评估报告。

2. 负责公告机构的主管机构应向委员会提交初步评估报告，委员会应立即将其转交给 MDCG 。

3. 按照本条第 2 段要求提交资料后 14 天内，委员会配合 MDCG ，从第 36 条所述清单中选出三个专家组成联合评估小组，如遇特殊情况，可更改数量。其中一位专家应为委员会的代表，协调联合评估小组的活动。另外两名专家应来自成员国，而不是申请机构所在地的其他成员国。

   联合评估小组应由能胜任符合性评估活动并了解申请中的器械类型的专家组成，特别是根据第 43（3）条启动该评估流程后，确保专业的问题可得到正确评估。

4. 联合评估小组应在委任后的 90 天内，审核根据第 34 条提交的申请文件。联合评估小组可向负责公告机构的主管机构提供关于申请及现场评估的反馈或要求其予以澄清。

   负责公告机构的主管机构以及联合评估小组应计划并实施对申请符合性评估的机构以及参与符合性评估过程的任何分支机构或分包商（欧盟内外）进行的现场评估。

   申请机构的现场评估应当由负责公告机构的主管机构主导。

5 在评估过程中如发现符合性评估申办机构不符合附录 VII 的要求则负责公告机构的主管机构和联合评估小组应予以重视，并本着达成共同意见的原则，弥合不同意见来评估该申请

   在现场评估结束时，负责公告机构的主管机构将向符合性评估申请机构列出评估产生的不符合项清单，并总结联合评估小组提供的评估意见。

   在规定的时间内，符合性评估申请机构应向国家主管机构提交纠正和预防性措施计划，以解决不符合项。

6 联合评估小组应在现场评估完成后 30 天内记录所有评估中存留的分歧意见， 并将这些告知负责公告机构的主管机构。

7. 负责公告机构的主管机构应当在收到申请机构提供的纠正和预防措施计划后，判断评估过程中发现的不符合项是否已经合理解决。该计划应指明已发现的不合格项的根本原因，并应加入一个执行纠正和预防措施的时间表。

   负责公告机构的主管机构在确认纠正和预防措施计划后，应将其以及相关意见转交给联合评估小组。 联合评估小组可要求负责公告机构的主管机构进一步澄清和修改。

   负责公告机构的主管机构应拟定其最终的评估报告，其中应包括：

   - 评估结果,
   - 确认已正确采取纠正和预防措施
   - 任何存留的与联合评估小组有分歧的意见, (在适用的情况下)
   - 建议的委任范围。

8. 负责公告机构的主管机构应向委员会，MDCG 和联合评估小组会提交最终评估报告和委任草案（如适用）。

9. 联合评估小组应在收到由负责公告机构的主管机构编制的评估报告和委任草案（如适用）后 21 天内，向委员会提供关于这些文件的最终意见，而委员会应立即将该最终意见提交给 MDCG。在收到联合评估小组的意见后 42 天内，MDCG 应对委任草案提出建议，负责公告机构的主管机构应在其做出委任决定时应对此建议予以适当考虑。

10. 委员会可通过实施细则，采取措施，制定第 34 条规定所指的申请委任的流程和报告详细安排，以及本条所规定的申请的评估。具体实施细则应按照第 107（3）条中所述的审查规程进行。

第 36 条

公告申请联合评估专家的提名

1. 成员国和委员会应提名医疗器械领域内具备符合性评估机构评估资格的专家参与第 35 条和第 44 条所述的活动。

2. 委员会应维护根据本条第 1 段提名的专家名单，以及专家的具体领域任职资格和专业能力的资料。该名单应当通过第 52 条所述的电子系统与成员国主管机构共享。

第 37 条

语言要求

根据第 34 条和第 35 条所需的所有文件应由一种或多种语言拟定，具体语言由成员国决定。

各成员国在应用第一段时，应考虑在全部或部分有关文件中使用医学领域通用易懂的语言。

委员会应根据第 29 和 30 条的规定提供文件的必要翻译，或者将部分语言变换成欧盟官方语言，使按照第 30（3）条要求指派的联合评估小组能够读懂并理解该文档。

第 38 条

委任和公告程序

1. 成员国只能委任已经按照第 35 条的要求进行评估并符合附录 VII 所列要求的符合性评估机构。

2. 成员国应使用委员会开发和管理的公告机构数据库内的电子公告工具（NANDO），将其委任的符合性评估机构通知委员会和其他成员国。

3. 使用本条第 13 段所述的代码，该通知应明确规定本法规所定义的符合性评估活动的委任范围，以及授权公告机构评估的器械类型，并在不影响第 40 条的情况下，明确所有与委任相关的情况。

4. 公告应附有负责公告机构的主管机构的最终评估报告，第 35（9）条所指联合评估小组的最终意见和 MDCG 的建议。若公告成员国不遵守 MDCG 的建议，应提供充分证据和理由。

5. 公告成员国在不影响第 40 条的情况下，应向委员会和其他成员国通报与委任有关的任何情况，并提供关于现有安排的书面证据，以确保公告机构被定期监督并持续满足附录 VII 中规定的要求。

6. 在第 2 段所指通知后 28 天内，成员国或委员会可就关于公告机构或负责公告机构的主管机构对其进行的监督提出书面异议并附以论据。若无反对意见，委员会应在接到第 2 段所指通知后 42 天内，在 NANDO 中发布该通知。

7. 当成员国或委员会根据第 6 段提出异议时，委员会应在第 6 段所述的期限到期后 10 天内将该事项提交 MDCG 。经各方协商后，MDCG 应至少在其收到该事项后 40 天内给出其意见。若 MDCG 的意见是接受此等通知，则委员会应在 14 天内，在 NANDO 中发布该通知。

8. 若 MDCG 在根据第 7 段进行磋商后，确认现有异议或提出另一异议，公告成员国应在收到 MDCG 意见后 40 天内做出书面答复。其答复内容应包括异议的解决办法，并将指定或不予指定该符合性评估机构的原因通知成员国。

9. 若公告成员国赞成委任符合性评估机构，并根据第 8 段给出其理由，委员会应在收到通知后 14 天内在 NANDO 中发布。

10. 当在 NANDO 中发布通知时，委员会还应在第 52 条所述的电子系统中增加该公告机构的公告信息，以及本条第 4 段中所述的文件，和本条第 7 和 8 段中所述的意见和答复。

11. 在 NANDO 中公布该通知之日起该委任命令即生效。发布的公告应注明公告机构的合法符合性评估活动。

12. 相关的符合性评估机构只有在委任命令按照第 11 条规定生效之后才能执行公告机构的认证活动。

13. 委员会应在 2017 年 11 月 26 日，通过实施细则，起草一份包括代码和相应器械类型的清单，以指定成员国公告机构的委任范围。这些实施细则应按照第 107（3）条中所所述的审查流程来实施。委员会在咨询 MDCG 之外，还可根据第 44 条所述的交流活动提供的信息更新本清单。

第 39 条

标识号和公告机构名单

1. 各公告机构在根据第 38（11）条规定生效后，则委员会应为其分配一个标识号。即使该机构已经在欧盟多个法案中已被指定，委员会也应为其指定一个单独的标识号。若根据本法规某机构成功被委任，同时其也是第 98/79/EC 指令指定的机构，则应保留原指令分配给其标识号。

2. 委员会将依据本法规制定公告机构名单，包括已经分配给它们的标识号以及本法规中定义的符合性评估活动以及公告的器械类型，这些在 NANDO 中向公众公开。该名单还应在第 52 条所述的电子系统中公布。委员会实时对列表进行更新。

第 40 条

公告机构的监督和重新评估

1. 对于可能影响其遵守附录 VII 所列要求的相关变化，或影响其执行被指定的符合性评估活动的能力的变化， 公告机构应最迟在 15 天内尽快向负责公告机构的主管机构通报。

2. 负责公告机构的主管机构应负责监督其境内公告机构及其分支机构和分包商，以确保其持续符合本法规的规定并履行其义务。公告机构应根据负责公告机构的主管机构的要求，向主管机构、委员会和其他成员国提供能够证明其符合所需的所有信息和文件。

3. 若委员会或成员国主管机构向另一成员国境内设立的公告机构提出涉及到该公告机构执行的符合性评估的请求，则其应向另一成员国公告机构的主管机构，发送一份该请求的副本。收到该要求后，相关公告机构应立即回复，最迟不超过 15 天。成员国负责公告机构的主管机构应确保任一其他成员国主管机构或委员会向其境内设立的公告机构提交的要求得到公告机构解决，除非有合法理由拒绝，此时可提交给 MDCG （医疗器械协调小组）处理。

4. 负责公告机构的主管机构对于各责任辖区内的公告机构（且在适用时应包含此等公告机构的分支机构及由其负责的分包商）是否仍然符合要求，以及是否履行了附录 VII 列出的职责，应至少每年重新审查一次。评审应包含对每一家公告机构（且必要时，对其分支机构和分包商）的现场审核。

负责公告机构的主管机构应按照年度评审计划执行监管和评审活动，以有效监督公告机构，确保其一直遵守本法规的要求。该计划应确定一个合理的时间表，对公告机构，特别是相关分支机构和分包商的受审频率做出规定。该主管机构应就其管辖的每家公告机构向 MDCG 和委员会提交年度监管或评审计划。

5. 负责公告机构的主管机构对公告机构的监管应包括对公告机构员工的现场监督审核，必要时还包括分支机构和分包商的员工（等同于在制造商的工厂内进行质量管理体系评估的人员） 。

6. 负责公告机构的主管机构对公告机构执行的监管应考虑其市场监管、警戒和上市后监管方面的数据，以对其进行帮助和指导。

负责公告机构的主管机构应制订一个追踪系统，用来处理投诉和其他信息（包括来自其他成员国的） ，这些信息可能反映公告机构未履行应尽义务，偏离常规或最佳行为准则。

7. 负责公告机构的主管机构除了定期监测或现场评审外，还可采取临时通知、飞行检查或“ 有因 ”核查的行动以便在有必要时解决特定问题或查证合规情况。

8. 负责公告机构的主管机构将评审公告机构对制造商的技术文件，特别是性能评估文

档的评估报告（在第 41 条中做进一步规定）。

9. 负责公告机构的主管机构应记录并存档有关公告机构不符合附录 VII 所列要求的任何调查结果并监督其及时采取补救和预防措施。

10. 自公告机构被委任之日起三年后，以及其后每隔 4 年一次，成员国负责公告机构的主管机构以及按照第 34 和 35 条所述程序任命的联合评审小组应全面重新评估设立于该国境内的公告机构，以确定其是否仍然符合附录 VII 的要求。

11. 委员会应有权按照第 108 条采纳授权法案以修订本条第 10 段进而修订待执行的该段所所述的全面重新评估的频率。

12. 成员国应当至少一年一次向委员会和 MDCG 报告有关对公告机构（适用时，包含其分支机构和分包商）开展监督和现场评估活动的情况。该报告应提供详细的记述这些活动的结果，包括根据第 7 段进行的活动，并且 MDCG 和委员应对报告履行保密义务，只将摘要部分予以公开。

该报告摘要应上传至第 52 条所指的电子系统。

第 41 条

对公告机构所评估的技术文件和性能评估报告的评审

1. 作为对公告机构现行监管的一部分，负责公告机构的主管机构，应审查一定数量的公告机构所评估的制造商技术文件，特别是性能评估文档报告，以验证公告机构根据制造商提供的信息所得出的结论。这些由负责公告机构的主管机构进行的评审包括现场和场外评审。

2. 经规划后，按照第 1 段审查的文件采样，并且由公告机构出具器械在类别和风险上应具有代表性的证明，尤其是高风险器械，抽样计划要恰当合理，负责公告机构的主管机构在需要时可将文件提交给 MDCG 。

3. 负责公告机构的主管机构应审核公告机构所做的评估是否恰当，并对流程、相关的文档及公告机构得出的结论进行检查。此等检查应包括公告机构作为评估依据的制造商的技术文件和性能评价文档。审核应使用 CS 进行。

4. 此等审核也应包括在公告机构的重新评估内，这与第 40（10）条，和第 43（3）条中所述的联合评估活动一致。执行这些审核应使用相应的专业知识。

5. 根据负责公告机构的主管机构或联合评估小组所做的审核和评审报告，和第 VII 章中所述来自市场监管、警戒和上市后监管活动的信息，或根据对技术发展的连续监测或有关器械安全与性能的关注点和突发事件，MDCG 可建议根据本条进行的抽样，应扩大或降低公告机构对技术文件和性能评估评审的比例。

6. 委员会可通过实施细则，制订本条所述技术文档和性能评估文档评审报告审查的详细安排、相关文件以及协调活动。这些实施细则应按照第 107（3）条中述及的审查规程实施。

第 42 条

委任与公告变更

1. 负责公告机构的主管机构应通知委员会和其他成员国关于公告机构委任的任何相关变更。

第 35 和 38 条扩大委任范围的程序应适用。

除扩大范围之外的委任变更，以下段落所述程序应适用。

2. 委员会应立即在 NANDO 中公布修订通告。委员会应立即就公告机构委任的变更录入相关信息到第 52 条所述电子系统中。

3. 若公告机构决定停止其符合性评估活动，应当尽快告知负责公告机构的主管机构和相关制造商，并且在停止评估活动前一年拟定停止计划。若另一公告机构已书面确认对这些证书涵盖的器械承担责任，则其资格证书在停止公告机构活动后九个月的期限内暂时有效。新的公告机构应在上述期限结束前完成对受影响器械的全面评估，方可为给这些器械签发新的证书。在公告机构终止其活动的情况下，负责公告机构的主管机构应撤销这一委任。

4. 若负责公告机构的主管机构已经确定公告机构不再符合列于附录 VII 的要求，或其未能履行自身义务，或没有执行必要的补救措施，主管机构则应依照其未达要求或不履行义务的严重程度，做出暂停、限制、或全部或部分撤销对该机构的委任的决定。一次暂停期限不得超过一年，但可追加一次同样期限的暂停。

负责公告机构的国家主管机构应立即通知委员会和其他成员国关于任何暂停、限制或撤销委任的情况。

5. 若委任已暂停、限制或全部或部分撤销，公告机构最迟应当在 10 天内告知相关制造商。

6. 若发生限制、暂停或撤销委任的情况，负责公告机构的主管机构应当采取适当措施，以确保有关公告机构的文件保留并提供给负责公告机构的其它成员国主管机构以及相关负责市场监管的主管机构。

7. 一旦出现限制、暂停或撤销委任的情况，负责公告机构的国家主管机构应该：

(a) 评估对公告机构签发证书的影响；

(b) 在发出委任变更通知的 3 个月内向委员会和其他成员国报告调查结果；

(c) 要求公告机构在主管机构决定的合理期限内暂停或撤销任何不当签发的证书以确保市场上的器械安全；

(d) 将其要求暂停或撤销的证书的相关信息录入第 52 条中所述的电子系统。

(e) 将其要求暂停或撤销的证书通过第 52 条中所述的电子系统通知制造商注册地址所在成员国的体外诊断医疗器械的主管机构。该主管机构应当采取适当措施，以在必要时避免给患者、使用者或其他人的健康或安全带来潜在风险。

8. 除了不当签发的证书外，当公告机构的委任被暂停或限制，证书在以下情况应该仍然有效：

(a) 负责公告机构的主管机构已经确认，暂停或限制期间的一个月内，受暂停或限制影响的证书没有出现安全问题，而且负责公告机构的主管机构已有相应的时间及行动计划以补救暂停或限制期间的公告机构的问题；或者

(b) 负责公告机构的主管机构已经确认在暂停或限制期间将不会签发、修订或重新签发证书，并且指出公告机构是否有能力继续监管或是否有能力对暂停或限制期间已签发的证书负责。若负责公告机构的国家主管机构认定公告机构没有能力支持现有已签发的证书，制造商应在暂停或限制 3 个月的时间内向证书覆盖的器械制造商登记营业的成员国境内体外诊断医疗器械主管机构书面确认，有其他合格的公告机构可临时承担公告机构的职能，监督并继续负责暂停或限制期间的证书。

9. 除了不当签发的证书外，当撤销公告机构的委任时，下列情况证书仍有 9 个月的有效期限：

(a) 若证书覆盖的器械制造商登记营业的成员国的体外诊断医疗器械主管机构已经确认没有发生与上述器械相关的安全问题，且

(b) 另一公告机构已书面确认，将立即承担这些器械的直接责任，并会在委任撤销起 12 个月内完成对它们的评估。

在第一子段所指情况下，证书覆盖的器械制造商登记营业的成员国的体外诊断医疗器械主管机构可将证书的临时有效期进一步延长 3 个月（总共不得超过 12 个月）。

如主管机构或公告机构认为委任变更可能会影响公告机构职能，应立即通知委员会、其他成员国及其他相关公告机构。

第 43 条

对公告机构资格的挑战

1. 委员会与 MDCG 应联合调查公告机构（或其一个 /多个分支机构或分包商）在持续履行附录 VII 所列要求或其应承担的义务时发生的问题。负责公告机构的主管机构应知悉这些问题并可做出调查。

2. 发出通告的成员国应按要求向委员会提供关于该公告机构委任的所有信息。

3 若对公告机构或分支机构或公告机构的分包商在持续履行附录 VII 所列要求方面有合理顾虑，而且主管机构的调查认为问题并没有被完全解决，或者应负责公告机构的主管机构的要求，委员会与 MDCG 一同，可启动（若适用的话）第 35(3) 和 (5)条所述的评审规程。该报告和这一评估的结果应遵循第 35 条的原则。另外，根据问题

的严重程度，委员会与 MDCG 可请求负责公告机构的主管机构允许最多两位专家（来自第 36 条规定的专家列表）参与现场评估，作为监察及监督计划的一部分，按照第 40 条以及第 40（4）条所述年度计划开展。

4. 若委员会确定公告机构不再符合其委任要求，应当相应地通知认证成员国，要求其采取必要的纠正措施，包括暂停、限制或必要时撤消委任。

凡成员国未能采取必要的纠正措施，委员会可通过实施细则来暂停、限制或撤销委任。细则的实施应按照第 107（3）条中述及的审查规程。委员会应当将相关决定通知有关成员国，并更新 UANDO 以及第 52 条所指电子系统。

5. 委员会应对调查过程中所获得的所有保密信息具有相应义务。

第 44 条

同行评审和负责公告机构的主管机构之间的经验交流

1. 委员会应为负责公告机构的主管机构提供经验交流及实践合作的机会。该交流应包括以下内容：

(a) 负责公告机构的主管机构的最佳工作指导文件的编制；

(b) 与本法规实施相关的公告机构指导性文件的开发；

(c) 第 36 条所述专家的培训和资格认定。

(d) 监控有关公告机构委任变更的动态趋势及公告机构之间证书撤销和转让的动态趋势；

(e) 监控第 38（13）条所述的范围代码的申请和适用情况；

(f) 制定主管机构与委员会之间的同行评审机制；

(g) 向公众传播主管机构和委员会对公告机构的监管和警戒活动的方法。

2. 负责公告机构的主管机构应当通过根据本条第 1 段所述的机制每三年参与一次同行评审。这些评审通常应在第 35 条说明的现场联合评估期间同步进行。此外，作为第 40 条所述监测活动的一部分，国家主管机构可选择是否进行此等评审。

3. 委员会应参加该组织，并为同行评审机制的实施提供支持。

4. 委员会应编制同行评审活动的年度总结报告并公开发表。

5. 委员会可通过实施细则，采取措施，制定本条所述的同行评审机制、培训和资格认定的详细安排与相关文件。应按照第 107（3）条中述及的审查规程来颁布实施细则。

第 45 条

公告机构的协调

委员会应确保公告机构之间适当的协调与合作落实到位，并按照第 2017/745 号法规第 49

条所述的公告机构协调小组的形式操作。

根据本法规所述公告机构应参与该小组的工作。

第 46 条

收费标准列表

公告机构应制定其所进行的符合性评估活动收费标准列表，并公开此等列表。

第 V 章

分类及符合性评估

第 1 节

分类

第 47 条

器械分类

1. 根据器械的预期目的及其内在风险，将器械分为 A、B、C 和 D 类。分类应按照附录 VIII 进行。

2. 由于使用的附录 VIII 而产生的制造商和相关公告机构之间的任何争议，应提交至制造商注册地所在成员国主管机构做出决定。对于在欧盟未注册也未指定授权代表的制造商，该事宜应提交至在附录 IX 第 2.2 节第 2 段（b）点最后一项中所述的授权代表注册地址所在成员国的主管机构。当有关公告机构和制造商成立于不同的成员国时，主管机构应在咨询委任该公告机构的成员国主管机构后方可通过其决定。

   制造商业务注册地所在国的主管机构应将相关决定通知 MDCG 及委员会。应根据要求公布分类决定。

3. 应成员国要求，委员会应在咨询 MDCG 后，通过实施细则，就以下项目做出决定：

   (a) 将附录 VIII 应用于器械、器械类别或分组，这些器械确定其分类；

   (b) 基于公共健康科学研究的新进展，或者基于在警戒和市场监管活动过程中发现的降低附录 VIII 的任何证据，可对器械、器械类别或分组进行重新分类。

4. 委员会也可在咨询 MDCG 后，通过实施细则，自行决定第 3 段（a）和（b）点涉及的问题。

5. 为保证附录 VIII 的统一适用，并考虑到相关科学委员会的相关科学性意见，委员会可采用实施细则，以解决实际应用中出现分歧问题。

6. 按照第 107（3）条的审查程序采用本条第 3、4 和 5 段中所述的实施细则。

第 2 节

符合性评估

第 48 条

符合性评估流程

1. 在器械投放市场前，依照附录 IX 到 XI 的符合性评估流程，制造商应对该器械符合性进行评估。

2. 在器械未投放市场前，除按照第 5（5）条生产的自制类器械外，依照附录 IX 到 XI 的符合性评估流程，制造商应对器械进行符合性评估。

3. 非性能研究用 D 类器械的制造商应按照附录 IX 的第 I、II（不包括第 5 节）和 III 章的规定进行符合性评估。

除了第 1 子段所述的规程，对于自测和床旁检测器械，制造商应遵循附录 IX 第 5.1 节规定的技术文件评估流程。

除了第 1 和 2 子段所述的规程，对于伴随诊断，公告机构应根据附录 IX 第 5.2 节规定的流程， 咨询由成员国根据欧洲议会和理事会第 2001/83/EC 号指令（1）指定的主管机构，或者欧洲药品管理局（ EMA ）（如适用）。

4. 非性能研究用 D 类器械的制造商，除了选用第 3 段规定的适用符合性评估流程外，还可选择应用附录 X 规定的符合性评估配合附录 XI 规定的符合性评估。

对于伴随诊断，公告机构应根据附录 X 第 3 节（k）点规定的流程，特别咨询由成员国根据欧洲议会和理事会第 2001/83/EC 号指令指定的主管机构，或者欧洲药品管理局（ EMA ）（如适用）。

5. 特别是，在不影响第 3 和 4 段所述其他规程规定的义务之外，根据第 100 条，如指定一个或多个参考实验室，执行符合性评估的公告机构将要求其中一家欧盟参考实验室根据适用的 CS、通过实验室测试验证制造商所声称的性能和承诺， 或按照制造商选择的至少与附录 IX 第 4.9 节和附录 X 第 3 节第（ j）点所述等效的其他方法来确保安全与性能水平。 由参考实验室执行的实验室测试应使用可获得的最佳参考品，并将分析的重点放在分析和诊断灵敏度上。

6. 除了第 3 和 4 段所述适当规程之外，若某 D 类器械无 CS 且该器械类型首次进行认证，公告机构应就制造商的性能评价报告咨询欧盟第 2017/745 号法规第 106a 条涉及的相关专家。为此，公告机构应在收到制造商性能评估报告的五天内将其提供给专家小组。有关专家应当在委员会的监督下，根据附录 IX 第 4.9 节或附录 X 第 3 节第（j）点适当规定， 参考实验室递交科学性意见的限期内向公告机构提供自己的意见。

7. 非性能研究用 C 类器械制造商应根据附录 IX 第 I 和 III 章规定，接受符合性评估，并且各同类器械组应评估至少一个典型器械的技术文件， 如该附录第 4.4 到 4.8 节的规定。

除了第 1 子段所述的规程， 对于自测类和床旁检测器械， 制造商应遵循附录 IX 第 5.1 节规定的技术文件评估流程。

除了第 1 和 2 子段所述的规程，对于伴随诊断，公告机构应为各器械，遵循附录 IX 第 5.2 节规定的技术文件评估流程， 并应用附录 IX 第 4.1 至 4.8 节规定的技术文件评估规程，同时应咨询由成员国按照第 2001/83/EC 号指令委任的主管机构，或按照附

录 IX 第 5.2 节规定的流程咨询欧洲药品管理局（ EMA ）（如适用）。

（1） 欧洲议会和理事会有关人用医疗产品的共同体守则的第 2001/83/EC 号指令， 2001 年 11 月 6 日（OJ L 311, 28.11.2001, P. 67）。

8. 非性能研究用 C 类器械制造商，可选择应用附录 X 规定的符合性评估配合附录 XI（第 5 节除外）规定的符合性评估，而非第 7 段规定的适用符合性评估流程。

对于伴随诊断，公告机构应特别为各器械，根据附录 IX 第 3 节第（ k）点的规定流程，咨询由成员国根据欧洲议会和理事会第 2001/83/EC 号指令指定的主管机构，或者欧洲药品管理局（ EMA ）（如适用）。

9. 非性能研究用 B 类器械制造商，应根据附录 IX 第 I 和 III 章规定接受符合性评估，并且各器械类别应评估至少一个典型器械的技术文件，如该附录第 4.4 到 4.8 节的规定。

除了第 1 子段所述的规程，对于自测和床旁检测器械，制造商应遵循附录 IX 第 5.1 节规定的技术文件评估流程。

10. 非性能研究用 A 类器械制造商在拟定附录 II 和 III 规定的技术文件后，将通过签发第 17 条所述的 EC 符合性声明，以声明其产品的符合性。

但是， 若器械在无菌条件下投放市场， 制造商应遵循附录 IX 或附录 XI 规定的流程。公告机构的参与仅限于建立、保护和保持无菌条件等方面。

11. 性能研究用器械应符合第 57 至 77 条的要求。

12. 成员国境内的公告机构可要求与第 1 至 10 段所述流程相关的所有或某些文件（包括技术文件、审查、评估和检验报告）应使用成员国决定的欧盟官方语言编写。如缺少此等要求，这些文件应该使用公告机构可接受的欧盟官方语言编写。

13. 委员会可通过实施细则规定详细安排和流程等方面，以确保公告机构在以下方面可协调应用符合性评估流程：

(a) 按照附录 IX 第 2.3 节第 3 段和第 3.5 节规定的代表性技术文件评估基础确定的 C 类器械的抽样频率及基本要求；

(b) 根据风险级别和器械类型，由公告机构按照附录 IX 第 3.4 节进行的飞行检查和抽样测试的最低频率；

(c) 拟送到按照附录 XI 第 4.12 节第 100 条和附录 XI 第 5.1 节指定欧盟参考实验室的 D 类器械生产样品或批次样品的抽样频率，或

(d) 在进行抽样测试、技术文件评估和型式检验时，公告机构按照附录 IX 第 3.4 和 4.3 节和附录 X 第 3 节第（ f）和（ g）点进行的物理、实验室或其他测试。

应按照第 107（3）条的检查流程实施第 1 子段所述的细则。

第 49 条

公告机构参与符合性评估流程

1. 如符合性评估流程需要公告机构的参与，制造商可申请选择公告机构，前提是该选

定机构已被安排开展器械类别相关符合性评估活动。制造商不能为同一符合性评估流程平行申请其他公告机构。

2. 在做出关于符合性评估决定前，有关公告机构应通过第 52 条中所述的电子系统将撤销其申请的制造商通知给其他公告机构。

3. 在按照第 1 段向公告机构申请时，制造商应在该公告机构决定之前声明其已经撤销了其他公告机构的申请，和/或提供先前已被其他公告机构拒绝的同一符合性评估的申请信息。

4. 公告机构可要求制造商提供任何信息或数据，以开展即定的符合性评估流程。

5. 公告机构以及公告机构人员必须具备执行符合性评估活动的最高级别职业操守、必备技术及专业领域的科学技能，并且能够抵抗一切压力和诱惑，特别是可能会影响其判断或符合性评估活动结果的资金问题，特别是对于这些活动的结果有利益关系的个人或集体。

第 50 条

D 类器械的符合性评估的审查机制

1. 公告机构应通知颁布证书的主管机构其已批准的 D 类器械，但无需通知补充或延续现有证书的情况。此类通知需参照第 52 条通过电子系统进行，并应增加第 20.4 节附录 I 所述的使用说明、第 29 条所述的安全与性能总结、公告机构的评估报告、以及（如适用）第 48(3) 条第 2 子段欧盟参考实验室的实验室测试和科学性意见，以及（如适用）依据第 48(4) 条的专家意见（参见欧盟第 2017/745 号法规第 106 条之规定），包括在公告机构和专家之间出现意见分歧时的完整论证。

2. 主管机构以及（在适当情况下）委员会可根据合理原因，根据第 40、41、42、43 或 89 条，开展进一步审查流程，并且在必要时，根据第 90 和 92 条采取适当的措施。

3. 在适当情况下，MDCG 和委员会可出于合理原因，要求专家小组就任何器械的安全性和性能给出科学建议。

第 51 条

符合性证书

1. 由公告机构根据附录 IX、X 和 XI 所颁发的证书应使用该公告机构所在成员国的欧盟官方语言或该公告机构可接受的其他欧盟官方语言编写。证书的最简内容见附录 XII 。

2. 证书的有效期为其列明的期限，不得超过五年。经制造商申请，证书的有效期可延长，但每次延期不得超过五年，同时需按照适用的符合性评估流程重新评估。证书的任何补充内容应与其补充的证书具有相同有效期。

3. 公告机构可限制器械应用于某些特定患者或使用者的预期目的，或要求制造商承担按照附录 XIII 第 B 部分规定进行上市后性能跟踪研究。

4. 若公告机构认定制造商不再满足本法规的要求，需考虑均衡原则，暂停或撤销颁发

的证书或对其施加限制，除非制造商在公告机构规定的时间内采取合适的措施保证遵守要求。该公告机构需给出其所作决定的理由。

5. 公告机构将所签发证书的相关信息录入第 52 条所述的电子系统，包括修订和补充以及证书的暂停、恢复、撤销或拒绝，和对证书的限制。此信息应向公众开放。

6. 随着技术进步，委员会有权按照第 108 条修订附录 XII 所列的证书最简内容。

第 52 条

公告机构和符合性证书的电子系统

为达成本法规目的，需按照欧盟第 2017/745 号法规第 57 条，在电子系统中核对并处理下列信息：

(a) 第 33（2）条所述分支机构名单；

(b) 第 36（2）条所述专家名单；

(c) 第 38（10）条所述公告和第 42(2)条所述修订公告相关信息；

(d) 第 39（2）条所述公告机构名单；

(e) 第 40（12）条所述总结报告；

(f) 第 50（1）条所述符合性评估公告及证书；

(g) 附录 VII 第 49（2）条和第 4.3 条节所述证书申请的撤回或拒绝；

(h) 第 51（5）条所述证书相关信息；

(i) 第 29 条所述安全与性能总结。

第 53 条

公告机构的自愿变更

1. 对于同一器械的符合性评估，若制造商终止与一家公告机构的合同，而与另一家公告机构签订合同，公告机构的变更详细安排需在制造商与即将达成协议的公告机构以及即将终止协议的公告机构之间的协议（如可行）中明确定义。协议应至少包含以下几个方面：

(a) 即将终止协议的公告机构颁发的证书失效日期；

(b) 在制造商提供的信息包括任何宣传资料中声明的即将终止协议的公告机构的标识号日期；

(c) 文件传输，包括机密性方面和产权；

(d) 即将终止协议的公告机构符合性评估任务委托给即将达成协议的公告机构的日期；

(e) 即将终止协议的公告机构负责的最后一个序列号或批号。

2. 在失效日期当日，即将终止协议的公告机构应撤销其为相关器械颁发的证书。

第 54 条

符合性评估流程的豁免

1. 通过豁免第 48 条，任何主管机构在正当理由要求下，可在成员国境内授权特定器械的市场投放或使用，无需执行该条所述流程，但其使用有利于公共健康或者患者安全或健康的要求。

2. 成员国在按照第 1 段做出授权任何器械投放市场和使用的决定后，应通知委员会和其他成员国，此类授权是批准使用而不针对单一患者。

3. 在按照本条第 2 段发布公告后，委员会针对公共健康或者患者安全或健康的特殊情况，可通过实施细则，在一定程度上延长成员国根据本条第 1 段在欧盟境内授权的时限，并设置器械可被投放市场或使用的条件。这些细则的实施应按照第 107（3）条中涉及的审查流程进行。

若存在攸关人类健康与安全的紧迫性理由，委员会应按照第 107（4）条涉及的流程立即采取适用的实施细则。

第 55 条

自由销售证书

1. 为出口目的，应制造商或授权代表要求，制造商或授权代表注册地所在成员国需签发一份自由销售证书，声明制造商或授权代表（如适用）依法在其境内登记营业地，并且根据本法规带有 CE 标记的器械可在欧盟上市销售。自由销售证书应列明提交至第 26 条规定的 UDI 数据库的器械基本 UDI-DI 。若公告机构颁发了符合第 51 条要求的证书，根据附录 XII 第 II 章第 3 节，自由销售证书应列出公告机构签发的唯一识别号以标识此证书。

2. 委员会可通过实施细则，建立一个自由销售证书模版，并考虑到自由销售证书的国际使用惯例。应按照第 107（2）条中涉及的审查流程通过这些实施细则。

第 VI 章

临床证据、性能评估和性能研究

第 56 条

性能评估和临床证据

1. 与附录 I 规定的相关通用安全和性能要求符合性的确认，特别是第 I 章和附录 I 第 9 节所指性能特征相关要求，在正常使用条件下的适用相关要求，以及附录 I 第 1 节和第 8 节涉及的干扰、交叉反应以及效益-风险比可接受性的评估，需基于科学有效性、分析和临床性能数据提供足够的临床证据（包括适用的附录 III 所指相关数据）。

制造商应规定并评价临床证据的水平，使其足以证明符合相关安全和性能基本要求。临床证据水平应适合器械特性及其预期用途。

为此，制造商应根据本条款及附录 XIII 第 A 部分计划、实施并记录性能评估。

2. 临床证据应支持器械制造商声称的预期用途，并应基于按照性能评估计划实施的一个持续的性能评估过程。

3. 根据本条款和附录 XIII 第 A 部分，性能评估应遵循明确且理论可行的程序证明以下内容：

(a) 科学有效性；

(b) 分析性能；

(c) 临床性能。

从这些要素评估中得出的数据和结论即构成该器械的临床证据。临床证据应当科学地证明在目前的医药水平下预期的临床效益是可实现的，并且器械足够安全。从性能评估得出的临床证据应当提供科学的有效保证，即在正常使用条件下满足附录 I 所列的通用安全与性能要求。

4. 应根据附录 XIII 第 A 部分第 2 节进行临床性能研究，除非有经充分验证的其他来源的临床性能数据。

5. 科学有效性数据、分析性能数据和临床性能数据，其评估和由此衍生的临床证据，应参照附录 XIII 第 A 部分第 3.2 节的性能评估报告进行记录。性能评估报告是附录 II 中器械相关技术文档的一部分。

6. 根据附录 XIII 第 B 部分，在器械的整个生命周期内，使用制造商 PMPF 计划中获得的数据更新性能评估及其文件记录，将作为第 79 条上市后监管计划的一部分。

C 类和 D 类器械的性能评估报告应在必要时进行更新，但至少每年更新一次第一子段所述的数据。第 29（1）条涉及的安全与性能总结必须尽快更新。

7. 在需确保附录 XIII 的统一应用时，委员会可因技术和科学进步的原因，采用实施细则解决分歧和实际应用中的问题。根据第 107（3）条中述及的审查规程颁布实施细则。

第 57 条

关于性能研究的一般要求

1. 除了性能研究所覆盖的内容以外，制造商还应保证器械的性能研究符合附录 I 规定的安全和性能基本要求，并且保证采取了一切预防措施来保障患者、使用者和其他人员的健康和安全。

2. 在适当情况下，性能研究应在与器械正常使用相似的环境中进行。

3. 性能研究的设计和实施必须在参与性能研究受试者的权利、安全、尊严和福祉得到保护并且优先于所有其他利益的基础上开展，产生的数据应科学有效、可靠、可信。

性能研究（包括使用剩余样品的性能研究）需依照数据保护的适用法律进行。

第 58 条

特定性能研究的附加要求

1. 任何性能研究

(a) 采集的外科有创标本只用于性能研究目的；

(b) 第 2 条第（ 46）点定义的干预性临床性能研究；或者

(c) 研究的开展涉及对受试者的额外侵入性流程或其他风险

除了须满足第 57 条和附录 XIII 要求外，还应当根据本条、第 59 至第 77 条和附录 XIV 进行设计、授权、实施、记录和报告。

2. 涉及伴随诊断的性能研究应执行与第 1 段相同的要求。 这并不适用于使用剩余样本进行的伴随诊断研究 - 但此类性能研究应通知主管机构。

3. 性能研究必须经过科学和伦理审查。 伦理审查应当由伦理委员会根据国家法律进行。各成员国应确保伦理委员会的审查流程与本法规对性能研究授权申请的评估流程一致。至少有一个非专业人士参加伦理审查。

4. 在性能研究的申办方未在欧盟境内登记时，该申办方应确保有一个在欧盟依法登记的自然人或法人作为其法定代表。该法定代表应负责确保申办方遵守本法规规定的义务，并成为本法规规定的申办方的所有通信的收件人。任何与法定代表的通信应视为是与申办方的通信。

成员国在其领土或第三国领土上单独进行性能研究时可选择不遵循第一子段要求，只要其保证申办方在其领土上至少设立一个联络人，该联络人作为本法规规定的申办方的所有通信收件人。

5. 在满足以下所有条件的情况下方可开展第 1 段所述的性能研究：

(a) 除非另有说明， 根据本法规规定， 性能研究需要待开展性能研究的成员国授权管辖；

(b) 根据国家法律成立的伦理委员会， 未根据该国法律在成员国全国范围内有效开展性能研究发表负面意见；

(c) 依据第 4 段，申办方或其法定代表或联系人在欧盟境内依法成立；

(d) 根据第 59 至 64 条，将对易感群体或受试者进行适当保护；

(e) 证明对受试者或公众健康的预期利益超过其可预见的风险和不便， 并持续监控该条件的符合性；

(f) 根据第 59 条，受试者或其法定代表（在受试者不能进行知情同意时）已给出知情同意。

(g) 向受试者或其法定代表 （在受试者不能进行知情同意时） 提供可在需要时接收更多信息的实体联系方式；

(h) 根据第 95/46/EC 号指令，保障受试者身心健全的权利、隐私权，并保护受试者个人数据；

(i) 在设计性能研究时应尽可能减少受试者的疼痛、 不适、恐惧及其他可预见风险，在性能研究计划中应明确风险阈值和压力水平并对其进行持续监控；

(j) 在性能研究条件下， 由有适当资质的医生负责向受试者提供医疗服务， 或在适

合时由国家法律授权的其他个人提供相关患者医疗服务；

(k) 受试者或其法定代表在参与性能研究时，不得受到不良影响（包括财务方面）；

(l) 在适当情况下，已对包括反映最新科学知识的生物安全性测试或鉴于器械使用目的其他必要测试进行测试；

(m) 考虑到现有技术水平，在进行临床性能研究时已对分析性能进行验证；

(n) 考虑到现有技术水平，在进行干预性临床性能研究时已证明其分析性能和科学有效性。对于尚未建立科学有效性的伴随诊断，应当提供生物标识物使用的科学依据；

(o) 考虑到现有技术水平以及在职业安全和事故预防方面的规定，已对器械使用的技术安全性进行证明；

(p) 符合附录 XIV 的要求。

6. 任何受试者或其法定代表（在受试者不能进行知情同意时），在不会产生损害的情况下，无需提供任何理由，可随时通过撤销其知情同意退出性能研究。在不违反 95/46/EC 指令情况下，知情同意的撤回不得影响已经开展的活动以及已经使用的在撤离前基于知情同意而获得的数据。

7. 研究者应从事相关成员国承认的职业，因其在患者护理或实验医学方面具有必要的科学知识和经验而认定其作为具有资格的研究者资质。为执行任务，参与性能研究的其他个人，应当在教育、培训或相关医疗领域和临床研究方法的经验方面具有合适资格。

8. 在合适的情况下，受试者参与的性能研究中使用的工具应适用于性能研究，并与器械预期使用的工具相似。

第 59 条

知情同意

1. 知情同意须由第 2 段（c）所述的进行面试的人员以及受试者或其法定代表（不能够给出知情同意时）在根据第 2 段进行充分知情后编写、注明日期并签名。当受试者不能编写时，可在至少有一名见证人在场的情况下，使用适当的替代方法记录，以给予同意。在这种情况下，见证人应在知情同意书上签名并注明日期。应当向受试者或其法定代表（在受试者不能给予知情同意时）提供该文件或记录（如适用）的副本以表示给予知情同意。知情同意应记录在案。应当给受试者或其法定代表充足的时间来考虑其是否决定参与性能研究。

2. 为获得知情同意而给予受试者或其法定代表（在受试者不能给予知情同意时）的信息应当：

(a) 使受试者或其法定代表理解

(i) 性能研究的性质、目的、效益、含义、风险和不便；

(ii) 受试者关于其受保护的权利和保障，尤其是其可在不产生任何损害的情况下拒绝参与并随时从性能研究中退出且无需提供任何理由的权利；

(iii) 性能研究进行的条件，包括受试者参与性能研究的预期持续时间；以及

(iv) 可能的治疗替代方案，包括受试者中止参与性能研究时的后续措施；

(b) 保持全面、简洁、清晰、相关和受试者或其法定代表可理解性；

(c) 在事先面试中须提供一位根据国家法律具有合适资格的调查小组成员；和

(d) 包括在第 65 条中所述的适用的损伤赔偿制度的信息；

(e) 包括第 66（1）条所指性能研究的欧盟范围单一识别编号，以及根据本条第 6 段有关性能研究结果可用的信息。

3. 第 2 段涉及的信息应以书面形式编写并提供给受试者或其法定代表（在受试者不能给予知情同意时）。

4. 在第 2 段（c）中所述的面试期间，应当特别注意特殊患者人群及个别受试者的信息以及提供信息的方式。

5. 在第 2 段（c）中所述的面试期间，应该确保受试者已经理解了信息。

6. 应告知受试者，根据第 73（5）条，无论性能研究的结果如何，性能研究和汇总报告将提交至第 69 条所所述的性能研究电子系统中，此等报告采用预期使用者可理解的术语编订，并且在报告可用时通知受试者。

7. 本法规要求，在不违背国家法律的前提下，参与性能研究除需获得法定代表的知情同意外，也需要取得能够给出意见并对给予的信息进行评估的未成年人的同意。

第 60 条

针对无行为能力受试者的性能研究

1. 无行为能力的受试者在其无行为能力发生前没有给予或拒绝给予知情同意时，除满足第 58（5）条规定的条件外，还需符合以下所有条件方可进行性能研究：

(a) 已获得其法定代表的知情同意；

(b) 无行为能力受试者以使其足以理解的方式获得第 59（2）条中所述的信息；

(c) 研究者应当尊重一个能够形成观点并对第 59（2）条的信息进行评估的无行为能力受试者明确拒绝参与或在任何时候退出性能研究的意愿；

(d) 除对参与性能研究直接相关的费用和收入损失进行补偿外，不得对受试者或其法定代表进行奖励或财务利诱；

(e) 性能研究对于无行为能力受试者是必不可少的，性能研究不能通过对能够给出知情同意的个人或通过其他研究方法获得同等有效性数据；

(f) 性能研究与受试者所患疾病直接相关；

(g) 预期参与性能研究将产生的结果是有科学根据的：

(i) 无行为能力受试者的直接利益抵消了所涉及的风险和负担；或者

(ii) 相比于对无行为能力受试者的标准疗法，当性能研究对相关无行为能力个体只会造成最小风险及负担时，相关无行为能力受试者所代表群体的一些利益。

2. 受试者应尽可能参与知情同意过程。

3. 第 1 段（g）（ii）不得违背更严格的国家法规，即在没有科学依据预期参与性能研究对受试者产生的直接利益大过其所涉及的风险和负担的情况下，禁止对无行为能力受试者进行性能研究。

第 61 条

针对未成年人的性能研究

1. 除了第 58（5）条规定的条件外，对未成年人的性能研究必须满足以下所有条件时方可开展：

(a) 已获得了其法定代表的知情同意；

(b) 未成年人以适应其年龄和心智成熟度的方式接受第 59（2）条涉及的信息，由经过培训或对儿童工作有经验的研究者或研究组提供；

(c) 研究者应当尊重一个能够形成观点并对第 59（2）条的信息进行评估的未成年人明确拒绝参与或在任何时候退出性能研究的意愿；

(d) 除对参与性能研究直接相关的费用和收入损失进行补偿外，不得对受试者或其法定代表进行奖励或财务利诱；

(e) 性能研究旨在考察仅在未成年人中出现的医学条件，或者性能研究对未成年人是必须的以验证在对能够给出知情同意个体的性能研究中或通过其他研究方法获得的数据；

(f) 性能研究与相关未成年人的医学条件直接有关，或本质上仅出现于未成年人；

(g) 预期参与性能研究将产生的结果是有科学根据的：

(i) 未成年人的直接利益抵消了所涉及的风险和负担；或者

(ii) 相比于对未成年人的标准疗法，当性能研究对相关未成年人只会造成最小风险及负担时，相关未成年人所代表群体的一些利益。

(h) 未成年人以适应其年龄和心理成熟度的方式参与知情同意过程；

(i) 若在性能研究期间，未成年人达到国家法律规定的能够给予知情同意的法定行为能力年龄，应当在受试者可继续参加性能研究之前取得其明确的知情同意。

2. 第 1 段（g）（ii）点不得违背更严格的国家法规，即在没有科学依据预期参与的性能研究对受试者产生的直接利益大过其所涉及的风险和负担的情况下，禁止对未成年人进行性能研究。

第 62 条

针对孕妇或哺乳期妇女的性能研究

针对孕妇或哺乳期妇女的性能研究，除需符合第 58（5）条设定的条件外，仅在满足以下条件时才能进行：

(a) 性能研究有可能对涉及的孕妇或哺乳期妇女，或其胚胎、胎儿或新生儿产生直接好处，且超过其所承担的风险和负担；

(b) 若此类性能研究对涉及的孕妇或哺乳期妇女，或其胚胎、胎儿或新生儿没有直接好处，则只能在满足下列条件时开展：

(i) 不得对非孕妇或哺乳期妇女进行可比有效性的性能研究；

(ii) 性能研究致力于使孕妇或哺乳期妇女、 或其他育龄妇女、 或其他胚胎、 胎儿或儿童受益；和

(iii) 性能研究对涉及的孕妇或哺乳期妇女或其胚胎、 胎儿或新生儿造成最小的风险和负担；

(c) 对进行研究的哺乳期妇女进行特殊护理，以避免对孩子的健康造成任何不利影响。

(d) 除对参与性能研究直接相关的费用和收入损失进行补偿外，不得对受试者进行奖励或财务利诱；

第 63 条

补充国家措施

对执行强制性兵役的人员、被剥夺自由的人员、因司法决定不能参加性能研究的人员或由社区福利院机构收容的人员，成员国可为其制定补充措施。

第 64 条

紧急情况下的性能研究

1. 通过豁免第 58（5）条（f）、第 60（1）条（a）和（b）以及第 61（1）条（a）和（b），可在决定入组受试者参加性能研究后，获取受试者参加性能研究的知情同意并提供性能研究信息，前提是根据该性能研究的临床性能研究计划，该决定是在受试者接受首次干预治疗时做出的，并且须满足以下所有条件：

(a) 由于突然危及生命或其他突发性严重医学状况造成的紧急情况， 受试者不能先提供知情同意，也不能先获取性能研究的信息；

(b) 参与性能研究对受试者可能产生直接临床相关好处的期望是具有科学依据的，如可测量的健康相关性改善，减轻痛苦，和 /或提高受试者的健康水平或疾病诊断；

(c) 在治疗窗口期内，无法先向其法定代表提供所有信息，并先获取知情同意；

(d) 研究者证明受试者此前未拒绝参与性能研究；

(e) 性能研究直接关系到受试者的健康状况，致使在治疗窗口期内无法事先获得受试者或其法定代表的知情同意并提供信息，而且性能研究还具有可能在紧急情况下单独进行的特性；

(f) 与受试者疾病的标准治疗相比，性能研究对受试者的风险和负担最小。

2. 按照本条第 1 段开展干预后，应根据第 59 条获得知情同意以便受试者能继续参与性能研究，并且应按照下述要求提供性能研究的相关信息：

(a) 对无行为能力的受试者及未成年人，研究者应获得其法定代表人的知情同意，不得拖延，并应尽快向受试者及其法定代表人提供第 59（2）条中涉及的信息；

(b) 对于其他受试者，研究者应获得受试者或其法定代表人的知情同意（以较快者为准），不得拖延，并应尽快向受试者或其法定代表人提供第 59（2）条中涉及的信息（以较快者为准）。

在根据（ b）获得法定代表知情同意的情况下，一旦受试者能够提供知情同意，应获得其对继续参与性能研究的知情同意。

3. 若受试者或其法定代表（如有）未同意，应告知其有反对使用性能研究所得数据的权利。

第 65 条

损害赔偿

1. 成员国应确保受试者在其领土上因参与性能研究而受到损害时有完善系统对其进行补偿，补偿形式包括保险、担保或具有相同目的并且与风险性质及程度相符的类似安排。

2. 申办方和研究者必须在其开展性能研究的成员国中以适用的形式使用第 1 段中所述的系统。

第 66 条

申请性能研究

1. 第 58（1）和（ 2）条中所述的性能研究申办方应输入并递交申请至性能研究拟开展的成员国（就本条目的而言，称为“ 相关成员国 ”），并按照附录 XIII 第 2 和 3 节和附录 XIV 的要求提交文件。

申请书应通过第 69 条中所述的电子系统提交，其将为该性能研究生成一个在欧盟范围内的唯一标识号，所有与性能研究相关的通讯都应使用此标识号。收到申请之日起 10 天内，根据附录 XIV 第 I 章，相关成员国应告知申办方该性能研究是否处于本法规范围内，以及申请卷宗是否完整。

2. 在附录 XIV 第 I 章中涉及的文件发生变化后一周内，申办方应在第 69 条所述的电子系统中更新相关数据并明确标示更改内容。应通过该电子系统告知有关成员国文件已更新。

3. 在相关成员国发现申请的性能研究不属于本法规范围或申请未完成时，应通过第 69 条所述的电子系统，通知申办方并给出最长 10 天时限供申办方回复意见或完成申请。成员国可酌情将该期限延长至 20 天。

若申办方未在上述时限内回复意见或完成申请，则该申请将视为失效。若申办方认为申请处于法规范围内和/或已完成，但相关成员国不同意，则视为申请被拒绝。相关成员国应提供申请被拒后的申诉流程。

相关成员国应在收到意见或要求补充的信息后五天内通知申办方性能研究是否处于本法规范围内和申请是否完成。

4. 有关成员国还可将第 1 段和第 3 段中的期限再延长 5 天。

5. 根据本章规定，按照第 1 段或第 3 段通知申办方的日期即为申请的确认日期。若申办方未收到通知，则确认日期应分别为第 1、3 和 4 段中所所述时间段的最后一天。

6. 在申请评估期间，成员国可要求申办方补充信息。首次提出要求至收到补充信息的时间将不计入第 7 段（b）点所规定的到期期限内。

7. 申办方可在下列情况下开始性能研究：

(a) 若性能研究根据第 58(1)第(a)点进行并且样品采集未对研究受试者带来重大临床风险，除非国家法律另有说明，否则在本条第 5 段所述的申请确认日期后并且有关成员国的性能研究主管伦理委员会未根据国家法律提出对整个成员国的否定意见后可开始；

(b) 若性能研究根据第 58(1)第(b)和(c)点和 58(2)条进行，或其不是本段第 (a)点中所述的性能研究，则在有关成员国向申办方发出授权通知并且有关成员国的性能研究主管伦理委员会未根据国家法律提出对整个成员国的否定意见后可开始。成员国应在第 5 段中所述的申请确认日期后 45 天内向申办方发出授权通知。成员国可将该期限延长 20 天以进行专家咨询。

8. 鉴于技术进步和全球法规发展，委员会有权按照第 108 条采用授权法案，对附录 XIV 第 I 章中所列的要求进行修订。为保证附录 XIV 第 I 章所列要求的统一适用性，委员会可采用实施细则，以解决分歧和实际应用中的问题。

9. 这些实施细则应根据第 107（3）条所述的检测规程采用。

第 67 条

成员国评估

1. 成员国应确保核实和评估申请的人员，或对其进行确定，不存在利益冲突，独立于申办方、相关研究者和为性能研究提供资金的自然人或法人，且无其他任何不正当的影响。

2. 成员国应确保评估由适当数量的具有必要资质和经验的人员共同完成。

3. 成员国应评估性能研究是否将对受试者或第三人的潜在剩余风险降至最低，在风险最小化后证明达到其预期临床益处的时间。 其应在考虑适用 CS 或统一标准所， 特别审查：

(a) 除了性能研究已覆盖的内容外， 还需证明性能研究的器械符合适用的通用安全与性能要求，以及在这些方面是否已采取保护受试者健康和安全的预防措施。这包括性能研究中的分析性能评估， 干预性临床性能研究中的分析性能、 临床性能和科学有效性评估，评估时应考虑现有技术的状态；

(b) 申办方是否采取了协调标准中的风险最小化方案，若申办方未使用协调标准，是否提供了与协调标准等效保护水平的风险最小化解决方案；

(c) 计划用于器械安全安装、投入使用和维护的性能研究的测量合理性是否足够；

(d) 性能研究产生数据的可靠性和稳定性， 注意考虑统计方法、 性能研究设计和方法论方面（包括样本量、对照和指标） ；

(e) 是否满足附录 XIV 的要求。

4. 如存在下列情况，成员国应拒绝对性能研究进行授权：

(a) 根据第 66（3）条递交的申请卷宗仍未完成；

(b) 器械或递交的文件， 特别是性能研究计划和研究者手册与科学知识不符， 以及性能研究无法为器械受试者或患者的安全性、性能特性或益处提供证据，或；

(c) 不满足第 58 条的要求，或

(d) 根据第 3 段进行的某些评估得出负面结果。

按照第一子段，成员国应提供此类申请被拒的申诉流程。

第 68 条

性能研究的实施

1. 申办方和研究者应确保性能研究按照经批准的性能研究计划进行。

2. 为确保受试者的权利、安全和福利得到保障、报告数据的可靠和稳定，以及性能研究的实施符合本法规的要求，申办方应确保对性能研究的实施进行充分监管。监管的程度和性质应由申办方根据对性能研究所有特性的评估来确定，所评估的特性包括：

(a) 性能研究的目标和方法，以及

(b) 与正常临床干预的偏离程度。

3. 申办方或研究者应对所有性能研究信息进行记录、加工、处理和保存（如适用） ，并在准确记录、解释和验证的同时，按照有关个人数据保护的适用法律保护所记录信息和受试者个人数据的保密性。

4. 应采取适当的技术和组织措施保护信息和个人资料免受非法侵入、披露、传播、修改、破坏或意外丢失，尤其是当处理过程涉及网络传输时。

5. 成员国应对适当水平的性能研究中心进行检查，确定性能研究是否根据本法规和所

批准的研究计划要求进行。

6. 申办方应制定应急程序，确保能立即识别在研究中使用的器械并在必要时立即召回。

第 69 条

性能研究电子系统

1. 委员会与成员国合作，建立、管理和维护电子系统：

(a) 为第 66（1）条所指性能研究生成唯一的标识号；

(b) 作为提交第 66、70、71、74 条涉及的所有性能研究的申请或公告和提交所有其他数据或数据处理的入口；

(c) 用于在成员国之间、成员国与委员会之间根据本法规进行与性能研究相关的信息交流（包括第 72 和 74 条涉及信息交换）；

(d) 供申办方按照第 73 条的规定提供相关信息，包括性能研究报告以及在其本条第 5 段中要求提供的总结；

(e) 用于报告第 76 条所述的严重不良事件、器械缺陷及相关更新。

2. 在设置本条第 1 段中所述的电子系统时，委员会应确保其与欧盟人用医药产品临床试验数据库能够共同使用，该数据库按照欧洲议会和理事会第 536/2014 号法规（[1]）第 81 条建立，同时废除了关于伴随诊断性能研究的第 2001/20/EC 号指令。

3. 对于第 1 段（c）点中所述的信息，只能对各成员国和委员会开放。该段其它要点应向公众开放，除非该信息的全部或部分因以下原因而需要进行合理保密：

(a) 按照欧盟第 45/2001 号法规保护个人数据；

(b) 保护商业机密信息，尤其是在研究者手册中特别考虑到器械符合性评估的状态，除非公开内容中有凌驾公共利益的信息；

(c) 成员国认为有利于对性能研究进行有效监管。

4. 不得公开受试者的个人数据。

5. 第 1 段所述的电子系统使用者界面应具有欧盟所有官方语言的版本。

第 70 条

携带 **CE** 标识的器械的性能研究

1. 若在预期目的范围内，开展性能研究，以便进一步评估已经根据第 18（1）条粘贴 CE 标识的器械（“ PMPF 研究 ”），并且若性能研究会对受试者带来器械正常使用条件下不会引发的手术，并且手术会引起创伤或相当复杂，则申办方应通过第 59 条所述的电子系统在其开始前至少 30 天通知相关成员国。进行通知。还应根据附录 XII 第 A 部分第 2 节和附录 XIII 提交相关文件。申办方应加入附录 XIII 第 A 部分第 2 节和附录 XIV 的所述的卷宗。第 58（5）条（ b）到（ l）和（ p）点和第 71、72 和 73 条和第 76（5）条以及附件 XIII 和 XIV 相关规定应适用于 PMPF 研究。

2. 若根据第 18（1）条已经携带 CE 标识的器械，在非预期目的范围内，开展性能研究，则第 58 至 77 条应适用。

（[1]） 欧洲议会和理事会于 2014 年 4月 16 日签发之关于人用医药产品的临床试验问题的第 536/2014 号指令，并废除第 2001/20/EC 号指令（ OJ L 158, 27.5.2014, p. 1）。

第 71 条

性能研究的实质性修改

1. 若申办方拟对性能研究提出可能对受试者的安全、健康或权利，或者研究数据的稳定性或可靠性产生重大影响的修改，则其应在一周内通过第 69 条所述的电子系统，通知开展或即将开展性能研究成员国修改的理由及性质。申办方应加入附录 XIV 所述相关文件的更新版本作为通知的一部分。相关卷宗更改应予以明确。

2. 成员国应按照第 67 条规定的程序评估性能研究的实质性修改。

3. 申办方可在第 1 段所指通知后最早 38 天实施第 1 段所述的修改，除非：

(a) 开展或即将开展性能研究的成员国根据第 67（4）条或者出于对公共健康、受试者和使用者安全或健康、或公共政策的考虑通知申办方拒绝该修改；或者

(b) 该成员国伦理委员会根据该成员国法律发布对整个成员国有效的否定对性能研究做出的实质修改意见。

4. 有关成员国可将第 3 段规定的期限延长 7 天以进行专家咨询。

第 72 条

成员国纠正措施和成员国之间性能研究的信息交流

1. 在开展或即将开展性能研究的成员国认为无法满足本法规的规定时，其至少应在其领土范围内采取以下措施：

(a) 撤销对性能研究的授权；

(b) 暂停或终止性能研究；

(c) 要求申办方修改性能研究的任何方面。

2. 在有关成员国采取第 1 段所述的任何措施之前，除需立即采取行动，应征询申办方和/或研究者的意见。应在七日内给出意见。

3. 在某成员国已采取本条第 1 段所述的措施时，或已拒绝性能研究，或已收到申办方通知因安全问题提前终止性能研究，该成员国应使用第 69 条所述的电子系统，向所有成员国和委员会传达相应决定及其理由。

4. 凡申办方在成员国做出决定之前撤回的申请，应使用第 69 条所述的电子系统通知所有成员国和委员会。

第 73 条

在性能研究结束、暂停或提前终止时的由申办方提供的信息

1. 若申办方已暂停性能研究或已提前终止性能研究，则应在 15 天内通过第 69 条所述的电子系统通知已暂停性能研究或已提前终止性能研究的成员国该暂停或提前终止。若申办方因安全问题暂停或提前终止性能研究，则应在 24 小时内通知即将开展性能研究的所有成员国。

2. 最后一位受试者的最后一次访诊应视为性能研究结束标识，除非性能研究计划规定了此等结束的其它时间点。

3. 申办方应通知开展性能研究的成员国此等性能研究的结束。通知应在与该成员国有关的性能研究结束的 15 日内发出。

4. 若在一个以上的成员国进行研究，申办方则应将性能研究结束的信息通知所有开展性能研究的成员国。通知应在性能研究结束的 15 日内发出。

5. 无论性能研究结果如何，在性能研究终止一年内或者在提前终止或临时暂停三个月内，申办方应向开展性能研究的成员国提交附录 XIII 第 A 部分第 2.3.3 节所述的性能研究报告。

与性能研究报告同时提交易于预期使用者理解的摘要。报告及摘要均由申办方使用第 69 条所述的电子系统提交。

如因科学原因，无法在研究结束一年内提交性能研究报告，则应在报告完成后尽快提交。在这种情况下，附录 XIII 第 A 部分第 2.3.2 节所述的临床性能研究计划应注明提交性能研究结果的时间及正当理由。

6. 委员会应发布性能研究报告摘要内容和结构的指导原则。

此外，委员会可发布关于原始数据格式和共享的指导原则，以供申办方自愿共享原始数据时参考。这些指导原则可作为基础并适用于现有性能研究领域原始数据共享指导原则（如可能）。

7. 根据第 3 段，报告和摘要将通过电子系统被公开访问，最迟为上市之前器械按照第 22b 条注册时。在提前终止或暂停的情况下，摘要和报告提交后可被立即公开访问。

若在摘要和报告根据第 3 段录入电子系统一年内，器械未按照第 22b 条注册，也将被公开访问。

第 74 条

性能研究的协调评估流程

1. 按第 69 条的规定，拟在多个成员国进行性能研究的申办方可通过第 66 条所述的电子系统提交单项申请，回复可通过电子方式传送给即将开展性能研究的所有成员国。

2. 进行第 1 段所指单项申请时，申办方应提议即将开展性能研究的成员国之一担任协调成员国。即将开展性能研究的成员国应在提交申请六天之内，商定其中一国担任协调成员国的角色。若各有关成员国未商定协调成员国，则由申办方提议的成员国担任。

3. 在第 2 段所述的协调成员国的指示下，有关成员国应协调其申请评估，特别是按照附录 XIV 第 I 章提交的文件。

但是，附录 XIV 第 I 章第 1.13、4.2、4.3 和 4.4 节以及附录 XIII 第 A 部分第 2.3.2 节所指卷宗完整性应由各成员国分别按照第 66（1）至（5）条评估。

4. 对于并非第 3 段第二子段所指卷宗，协调成员国应：

(a) 在收到单项申请 6 天之内通知申办方其为协调成员国（通告日期）；

(b) 对于本申请的验证，应考虑通告日期 7 天内由相关成员国提交的注意事项。

(c) 在通告日期起 10 日内，评估性能研究是否属于本法规范围内及该申请是否完整，并应相应通知申办方。第 66（1）和（ 3）至（ 5）条应适用于评估相关的协调成员国；

(d) 在评估报告草案中给出其评估结果，并在有关成员国确认日期后 26 日内传播。直至确认日期第 38 日，其他有关成员国可将评估报告草案和初始申请的相关意见和建议提交至协调成员国，且应在最终评估报告最后定稿时充分考虑这些备注和提案，并在申办方和有关成员国确认日期 45 日内进行提交。

所有相关成员国在根据第 66（7）条决定申办方申请时，应考虑最终评估报告。

5. 在第 3 段第二子段所指相关文件的评估由各成员国单独进行，个别情况下，各相关成员国可要求申办方提供额外信息。申办方应在有关成员国规定的期限内提交要求的额外信息，该日期不得超过收到请求之日起 12 天。第 4 段（ b）点规定的最后一个截止期限应从收到请求之日起暂停至收到额外信息。

6. 对于归为 C 类和 D 类的器械，协调成员国可将第 3 段规定的期限额外延长 50 天以进行专家咨询。

7. 委员会可通过实施细则，进一步规定协调评估流程和时间表，在决定申办方申请时，有关成员国应将此纳入考虑。 实施细则还可包括有关本条第 12 段重大更改的协调评估流程和时间表，有关第 76(4)条的不良事件报告，并且涉及伴随诊断的性能研究，根据欧盟第 536/2014 号法规通过临床试验对医疗产品进行的协调评估。 应按照第 107（3）条规定的审查流程通过这些实施细则。

8. 当涉及协调评估领域的协调成员国的结论为可接受进行性能研究或可接受的受试者符合特定条件，该结论应视为所有有关成员国的结论。

尽管有第一子段规定，有关成员国可对协调成员国协调评估的结论提出异议，但仅限于以下理由：

(a) 当其认为参与性能研究将导致受试者在有关成员国接受的治疗低于正常临床实践；

(b) 违反国家法律；或

(c) 存在对受试者安全性和根据第 4 段(d)提交数据的可靠性和稳定性的顾虑。

在本段第二子段基础上，凡有关成员国一国对结论持有异议的，应通过第 51 条所述的电子系统向委员会、所有其他有关成员国及申办方传达其异议及详细理由。

9. 若关于协调评估的协调成员国报告的结论为性能研究不可接受，该结论应被视为所有相关成员国的结论。

10. 若有关成员国因第 8 段第二子段的任何理由，对协调成员国的结论持有异议，则应拒绝授权性能研究，或若其发现（且理由正当），即附录 XIV 第 I 章第 1.13、4.2.、4.3.及 4.4.节强调的各方面未得到遵守，或伦理委员会已给出关于性能研究的否定意见，且该意见按照国家法律对整个成员国有效。成员国应提供此类申请被拒后的申诉流程。

11. 各有关成员国应通过第 69 条所述的电子系统通知申办方：是否已授权性能研究、是否授权受条件限制或是否拒绝授权。应从提交之日五天内，由负责最终评估报告的协调成员国根据本条第 4 段(d)点，通过单一决定的方式发送通告。若基于条件的性能研究授权仅限于在该授权时不能满足其性质的条件下执行。

12. 第 71 条所述的实质性修改应通过第 69 条所述的电子系统通知相关成员国。对于本条第 8 段第二子段所述是否有理由拒绝任何评估，应在协调成员国的指导下进行，对附录 XIV 第 I 章第 1.13.、4.2.、4.3.和 4.4.以及附录 XIII 第 A 部分第 2.3.2.节的内容做出的实质性修改应由相关成员国单独评估。

13. 委员会应在协调成员国完成本章规定的任务时向其提供行政支持。

14. 本条给出的流程应在 2029 年 5 月 27 日前，仅适用于待开展性能研究且同意应用本法规的成员国。在 2029 年 5 月 27 日后，要求所有成员国应用该流程。

第 75 条

审查协调评估流程

截止 2028 年 5 月 27 日，委员会应向欧洲议会和理事会提交一份关于应用第 74 条所获经验的报告，并在必要时提出对第 74(14)条和第 113（3）条（ g）点的审查。

第 76 条

记录并报告性能研究期间发生的不良事件

1. 申办方应充分记录以下所有情况：

(a) 在性能研究计划中发现对性能研究结果的评估至关重要的任何不良事件类型；

(b) 任何严重不良事件；

(c) 任何如未采取适当措施、未发生干预或情况不利时，可能导致严重不良事件的器械缺陷；

(d) 任何与（ a）至（ c）点所所述的任何事件有关的新发现。

2. 申办方应通过第 69 条所所述的电子系统，向进行性能研究的所有成员国报告以下内容，且不得有任何延误：

(a) 任何与该器械、对照产品或研究流程具有因果关系的严重不良事件，或者其他有可能发生类似因果关系的情况；

(b) 任何如未采取适当措施、未发生干预或情况不利时，可能导致严重不良事件的器械缺陷；

(c) 任何与（a）和（b）点所所述的任何事件有关的新发现。

报告的时间周期应考虑事件的严重性。必要时，为确保及时报告，申办方可先提交初步的不完整报告，后续提交完整报告。

根据任何即将开展性能研究的成员国要求，申办方应提供第 1 段中所述的所有信息。

3. 申办方还应通过第 69 条所述的电子系统方式，向即将开展性能研究的成员国报告本条第 2 段所所述的任何已发生事件，即使用相同临床性能研究计划在第三类国家进行的性能研究中出现的此类事件。

4. 对于申办方根据第 74 条所所述的单项申请而执行的性能研究，申办方应通过第 69 条所述的电子系统报告本条第 2 段涉及的任何事件。一旦收到后，本报告应以电子方式传送给所有即将开展性能研究的成员国。

在第 74（2）条所所述协调成员国的指导下，成员国应协调其对严重不良事件和器械缺陷的评估，以确定是否需要对性能研究进行修改、暂停或终止或取消该性能研究的授权。

本段不得影响其他成员国为确保对公共卫生和患者安全的保障，根据本法规自行执行评估和采取措施的权利。并应随时通知协调成员国和委员会任何此类评估的结果以及采取的任何此类措施。

5. 对于第 70（1）条所所述的 PMPF，应执行第 82 条至第 85 条以及根据第 86 条采取的实施细则规定的有关警戒的规定，而非本条。

6. 尽管有第 5 段的规定，本条应适用于在严重不良事件和上述性能研究之间已经确立因果关系的情况。

第 77 条

实施细则

委员会可通过实施细则，建立实施本章所需的详细安排和程序，包括以下内容：

(a) 用于第 66 条和第 74 条所所述的性能研究及其评估申请的统一电子表格，要考虑到具体类别或器械组别；

(b) 第 69 条所所述电子系统的运行；

(c) 用于通告第 70（1）条所所述的 PMPF 和第 71 条所所述的实质性修改的统一电子表格；

(d) 第 72 条所述成员国之间的信息交流；

(e) 用于报告第 76 条所述严重不良事件和器械缺陷的统一电子表格；

(f) 考虑到第 76 条所述报告事件的严重性，用于报告严重不良事件和器械缺陷的时间表；

(g) 有关临床证据/数据要求的统一应用，以证明符合附录 I 所规定的通用安全与性能要求。

第一段所指实施细则应在与第 107（3）条中述及的审查流程保持一致的条件下施行。

第 VII 章

上市后监管、警戒和市场监管

第 1 节

上市后监管

第 78 条

制造商的上市后监管体系

1. 根据第 10（8）条的规定，对于任何器械，制造商应采用与风险等级相称并且适用于该器械类型的方式来计划、建立、记录、实施、维护和更新上市后的监管体系，该体系应属于制造商质量管理体系的组成部分。

2. 上市后的监管体系应积极和系统地适用于收集、记录并分析器械在其整个生命周期内的质量、性能和安全相关数据，以得出必要的结论，并确定、实施和监测任何预防及纠正措施。

3. 由制造商的上市后监管体系收集的数据应着重用于：

   (a) 更新效益风险测定，改善风险管理，如附录 I 第 I 章所述

   (b) 更新设计和制造信息、使用和标签说明；

   (c) 更新性能评价；

   (d) 更新第 29 条所述的安全与性能概要；

   (e) 用于确立预防、整改或现场安全纠正措施要求；

   (f) 用于确立提高器械的可用性、性能和安全性的意见；

   (g) 当相关时，有助于其他器械的上市后监管；及

   (h) 根据第 83 条要求监测并报告的趋势。

   技术文件应进行相应的更新。

4. 若在上市后监管的过程中确定需要采取预防和/或纠正措施，制造商应实施适当的措施，并通知相关主管机构和公告机构（如适用）。当发现严重事件或实施现场安全纠正措施时，应按照第 82 条所述进行报告。

第 79 条

上市后监管计划

第 78 条所述的上市后监管体系应以上市后监管计划为基础，其要求位于附录 III 的第 1 节。上市后监管计划应属于附录 II 所规定技术文件的一部分。

第 80 条

上市后监管报告

A 类和 B 类器械的制造商应编制一份上市后监管报告，总结根据第 79 条所述上市后监管计划收集的上市后监管数据的分析结果和结论，以及采取任何预防和纠正措施的理由和说明。

应在必要时对报告进行更新，并应按照相应要求提供给公告机构和主管机构。

第 81 条

定期安全性更新报告

1. 每种器械以及相关的各类别或组别的器械、C 类和 D 类器械的制造商应编制定期安全性更新报告（“PSUR”），总结根据第 79 条所述上市后监管计划收集的上市后监管数据的分析结果和结论，以及采取任何预防和纠正措施的理由和说明。

在该器械的整个生命周期内，本 PSUR 应列出：

(a) 效益风险监测的结论；

(b) 上市后性能跟踪报告（PMPF）的主要结果；以及

(c) 器械的销售量和使用器械的群体规模与其他特性的评估，以及实际运行时器械的使用频率。

C 类和 D 类器械的制造商应至少每年对 PSUR 进行更新。PSUR 应属于附录 II 和 III 中所规定技术文件中的一部分。

2. D 类器械的制造商应通过第 87 条所述电子系统的方式，并根据第 48 条所述向参与符合性评估的公告机构提交 PSUR。公告机构应审查该报告，并将其评估添加到该电子系统中，评估中应包括采取任何措施的细节。PSUR 和公告机构的评估应通过电子系统提供给主管机构。

3. C 类器械制造商应向参与符合性评估的公告机构提交 PSUR，并应主管机构要求向其提供报告。

第 2 节

警戒

第 82 条

报告严重事件和现场安全纠正措施

1. 在欧盟市场提供器械的制造商，除了应报告器械进行的性能研究外，还应根据第 87(5) 和 (7) 条规定，向相关主管机构报告以下内容：

(a) 任何涉及在欧盟市场上所提供器械的严重事件，除了在产品信息和技术文件中清楚记录并量化的预期错误结果，此类事件应根据第 83 条进行趋势报告；

(b) 任何有关欧盟市场上销售器械的现场安全纠正措施，若现场安全纠正措施的原因并不仅限于在第三国销售的器械，则包括第三国对在欧盟市场上合法提供的器械所采取的任何现场安全纠正措施。

在第 1 子段内所述的报告应通过第 87 条所述的电子系统提交。

2. 作为一般规则，第 1 段所述的报告时间段应考虑到严重事件的严重性。

3. 制造商应在确认事件与其器械因果关系或者此类因果关系是合理可能之后，且不得

迟于其察觉到严重事件后的 15 天立即报告（ a）点中所述的任何严重事件。

4. 尽管有第 3 段的规定，若出现第 1 段所述的严重的公共卫生威胁，则应立即报告，且不迟于制造商察觉到此威胁后 2 天。

5. 尽管有第 3 段的规定，若出现人员死亡或意外的健康状况严重恶化，该报告应在制造商确认或怀疑器械与严重事件之间的因果关系后立即提供，且不迟于察觉到该严重事件之日后 10 天。

6. 必要时，为确保报告的及时性，制造商可先提交初步的不完整报告，后续提交完整报告。

7. 若在察觉到潜在可报告事件，但制造商不确定该事件是否应报告，制造商依然应在第 2 至 5 段规定之时限内提交报告。

8. 除非紧急情况下制造商需要立即采取现场安全纠正措施，否则制造商应在报告第 1 段（b）点所述的现场安全纠正措施之后，实施现场安全纠正措施。

9. 对于使用相同或相同类型器械出现的类似严重事件，并且已经确定了其根本原因或实施了现场安全纠正措施，或者该事件属于较常见并且已经记录完好，制造商可提供定期汇总报告，代替个别严重事件报告，但条件是第 84（9）条所述的协调主管机构已经向第 87（8）条（ a）和（ b）点所述的主管机构咨询，并同意制造商提供定期汇总报告的格式、内容和频率。若第 87（8）条（ a）和（ b）点中仅所述单一主管机构，则制造商可根据与该主管机构达成协议，提供定期汇总报告。

10. 成员国应采取适当措施，例如组织有针对性的宣传活动，以鼓励并使得医护专业人员、使用者和患者能够向其主管机构报告第 1 段（ a）点所述的可疑严重事件。

主管机构应记录其在国家层面集中收到的来自健康专业人士、 使用者和患者的报告。

11. 若成员国的主管机构获得此类来自健康专业人士、使用者和患者的有关第 1 段（ a）点所述的可疑严重事件的报告，则它应采取必要步骤，确保立即向相关器械制造商通报可疑的严重事件。

若相关器械制造商认为事件属于严重等级，应根据本条第 1 至 5 段，向发生严重事件的成员国主管机构提供有关该等严重事件的报告， 并应根据第 84 条采取适当的后续行动。

若相关器械制造商认为事件并不属于严重事件或应当视为不良预后的发展，则该事件将由第 83 条的趋势报告所涵盖，并应提供解释性说明。

若主管机构不同意解释性说明的结论，则可能要求制造商根据本条第 1 至 5 段提供报告，并要求制造商根据第 84 条确保采取适当跟踪措施。

第 83 条

趋势报告

1. 制造商应通过第 87 条所述的电子系统报告非严重事件发生频率或严重程度的任何统计学上显著性增加， 这些事件可能对附录 I 第 1 节和第 5 节所所述风险效益分析产生重大影响，且已经导致或可能对患者、使用者或其他人的健康或安全造成不可接受

的风险，或者与器械规定性能（根据附录 I 第 9.1 节（a）和（b）点以及在技术文件和产品信息中规定）相比已确认预期错误结果的任何显著增加。

在参照第 79 条制订的上市后监管计划中，制造商应定义如何管理第 1 子段所述的此类事件和用于确定此类事件频率或严重程度在统计学上显著增加的方法或性能变化，以及观察期长度。

2. 主管机构可对第 1 段所述的趋势报告自己进行评估，并要求制造商根据本法规采取适当措施，确保保护公众健康和患者安全。主管机构应向委员会、其他主管机构以及颁发证书的公告机构，通知此类评估结果和采取的此类措施。

第 84 条

严重事件分析和现场安全纠正措施

1. 在根据第 82（1）条报告严重事件后，制造商应立即对严重事件和相关器械进行必要的相关调查。这应包括对事件和现场安全纠正措施的风险评估，并酌情考虑本条第 3 段所述标准。

在将此类措施通知主管机构之前，制造商应在第一子段所述调查期间与主管机构以及在适当时与相关的公告机构合作，并且不得执行任何涉及更改器械或相关批次样品的调查，因为这可能会影响后续对事件原因的评估。

2. 成员国应采取必要措施，确保任何有关在其境内出现严重事件的信息或在其境内已经或将要执行的现场安全纠正措施，这些措施均根据其理解并按照第 82 条的说明，在国家层面由其主管机构评估，如可能可与制造商、相关公告机构在适当时一起进行集中评估。

3. 在第 2 段所述的评估范围内，主管机构应评估所报告严重事件，并评估现场安全纠正措施所产生的风险，并同时考虑公共卫生的防护和标准，例如问题复发的因果关系、可检测性和概率、器械的使用频率、直接或间接伤害的发生概率和严重程度、器械的临床效益、预期和潜在使用者以及受影响人群。同时主管机构还应评估制造商设想或采取现场安全纠正措施的适当性，对任何其他纠正措施的需要及其种类，特别应考虑到附录 I 所规定的本质安全原则。

根据国家主管机构的要求，制造商应提供风险评估所需的所有文件。

4. 主管机构应监控制造商对严重事件的调查。必要时，主管机构可干预制造商的调查或独立进行调查。

5. 制造商应通过第 87 条所所述的电子系统，向主管机构提供陈述其调查结果的最终报告。该报告应列出结论，以及何处应采取纠正措施。

6. 若为伴随诊断，本条第 9 段所述的评估主管机构或协调主管机构应根据公告机构是否按照附录 VIX 第 5.2 节和附录 X 第 3.11 节中规定的流程，咨询管理医疗产品的成员国相关主管机构或欧洲药品管理局（EMA），并适当通知国家主管机构或 EMA 。

7. 在根据本条第 3 段实施评估后，评估主管机构应通过第 87 条所述的电子系统，立即通知其他主管机构由制造商采取或要求制造商采取的措施，以尽量减少严重事件的重现风险，包括根本严重事件的信息及其评估结果。

8. 制造商应使用现场安全通告，及时将有关现场安全纠正措施的信息提请有关器械使用者注意。现场安全通告应采用欧盟官方语言或由采用现场安全纠正措施的成员国确定的语言编辑。除紧急情况外，现场安全通告草案的内容应提交评估主管机构，或对于第 9 段所所述的情况，协调主管机构应允许其提出意见。除非个别成员国有正当理由，否则现场安全通告的内容在所有成员国中应保持一致。

现场安全通告应能够正确识别所涉及的器械，特别是包括相关 UDI，以及执行现场安全纠正措施的制造商，特别是包括 SRN（若已签发）。现场安全通告应被清楚解释，且不会淡化风险水平，有关器械故障的现场安全纠正措施的原因以及患者、使用者或其他人的相关风险，应清楚表明所有使用者应采取的措施。

制造商应在第 87 条所述的电子系统中输入现场安全通告内容，并向公众开放。

9. 主管机构应主动参与相关程序，以便根据第 3 段所述协调评估以下情况：

(a) 若存在特定严重事件或多个相同制造商的同一或同一类型器械在多个成员国中的严重事件；

(b) 若制造商在多个成员国提出的现场安全纠正措施的适当性存在问题。

该协调程序应涵盖以下内容：

- 必要时，根据具体情况委任协调主管机构；
- 定义协调评估过程，包括协调主管机构以及其他主管机构参与的任务和责任。

除非主管机构另有协议，否则协调主管机构应属于制造商注册营业地点所在成员国的主管机构。

协调主管机构应通过第 87 条所所述的电子系统通知制造商、其他主管机构和委员会其已经承担了协调机构的作用。

10. 协调主管机构的指定不得影响其他主管机构为确保保护公共卫生和患者安全而根据本法规自己执行评估和采取措施的权利。并应随时通知协调主管机构和委员会任何此类评定的结果以及采取的任何此类措施。

11. 委员会应在协调主管机构根据本章完成任务时提供行政支持。

第 85 条

警戒数据分析

委员会应与成员国合作，落实体系和程序，主动监测第 87 条所所述电子系统中可用的数据，以发现数据中可能发现的新风险或安全问题的趋势、模式或信号。

当发现以前未知的风险或预期风险的频率将对风险收益的确定产生显著不利的改变时，主管机构或协调主管机构应适时通知制造商或授权代表，随后采取必要的纠正措施。

第 86 条

实施细则

委员会可通过实施详细安排，并在咨询 MDCG 后，采取实施第 80 条至第 85 和 87 条所需的模式和流程，其中应涉及以下方面：

(a) 严重事件和现场安全纠正措施的类型学和有关特定器械或器械类别或组别的关联；

(b) 第 80、81、82、83 和 84 条分别所所述严重事件和现场安全纠正措施的报告和现场安全通告，以及提供定期汇总报告、上市后监管报告、定期安全性更新报告（PSUR）以及趋势报告；

(c) 用于电子和非电子报告的标准结构表格，包括由医护专业人员、使用者和患者所报告可疑严重事件的最小资料集；

(d) 考虑到第 82 条所述事件的严重性，用于报告现场安全纠正措施、制造商提供定期汇总报告和趋势报告的时间表；

(e) 第 84 条所述主管机构之间交流信息的协调表格；

(f) 指定协调主管机构的流程；协调评估过程；协调主管机构以及其他主管机构参与这一进程，包括任务和责任。

应按照第 107（3）条中述及的审查规程通过第 1 段所述的实施细则。

第 87 条

有关警戒和上市后监管的电子系统

1. 委员会应与成员国合作，设置并管理电子系统以整理并处理以下信息：

(a) 制造商关于第 82（1）条和第 84（5）条所述严重事件和现场安全纠正措施的报告；

(b) 第 82（9）条所所述制造商的定期汇总报告；

(c) 制造商关于第 83 条所所述的趋势报告；

(d) 第 81 条所所述的定期安全更新报告（ PSUR）；

(e) 第 84（8）条所所述制造商的现场安全通告；

(f) 根据第 84（7）和（9）条，成员国主管机构之间以及它们与委员会之间的交换信息。

该电子系统应在 UDI 数据库中加入相关链接。

2. 本条第 1 段所述的信息应通过电子系统提交给成员国主管机构和委员会。根据第 49 条，公告机构还应拥有访问权限，可访问其所签发证书的器械的相关信息。

3. 委员会应确保医护专业人员和公众对第 1 段所述的电子系统具有适当的访问权限。

4. 根据委员会与第三类国家或国际组织主管机构之间的约定，委员会可授予此类主管机构或国际组织在适当级别访问第 1 段所述的电子系统。这些约定应以互惠为基础，

并提供与适用于欧盟等同的保密和数据保护。

5. 第 82（1）条（ a）点所所述的严重事件报告应在收到后通过本条第 1 段所述电子系统自动传送至发生事件的成员国主管机构。

6. 第 83（1）条所所述的趋势报告应在收到后通过本条第 1 段所述的电子系统自动传送至发生事件的成员国主管机构。

7. 第 82（1）条（ b）所所述的现场安全纠正措施报告应在收到后通过本条第 1 段所述的电子系统自动传送至下列成员国的主管机构：

(a) 正在或将要执行现场安全纠正措施的成员国；

(b) 制造商拥有其注册营业地点的成员国。

8. 第 82（9）条所所述的定期汇总报告应在收到后通过本条第 1 段所述的电子系统自动传送至下列主管机构：

(a) 根据第 84（9）条参与协调程序并同意定期汇总报告的成员国；

(b) 制造商拥有其注册营业地点的成员国。

9. 本条第 5 至 8 段所所述的信息应在收到后通过本条第 1 段所述的电子系统自动传送至根据第 51 条为有关器械颁发证书的公告机构。

第 **3** 节

市场监管

第 88 条

市场监管活动

1. 主管机构应对器械的符合性特性和性能执行适当的检查，包括酌情审查文件以及基于适当样品的物理或实验室检查。 主管机构应特别考虑到有关风险评估和风险管理、警戒数据和投诉的既定原则。

2. 主管机构应制定年度监管活动计划，并分配足够数量的物质和胜任人力资源以执行这些活动，同时应根据第 99 条和当地条件，执行由 MDCG 制定的欧洲市场监管方案。

3. 为满足第 1 段规定的义务，主管机构：

(a) 可特别要求经济运营商提供开展主管机构规定活动所必需的文件和信息， 在必要时提供必要的器械或可免费使用的器械；和

(b) 对经济运营商以及供应商和 /或分包商的营业场所， 对专业使用者的设施 （必要时），进行通知和突击检查（如有必要） 。

4. 主管机构应起草监管活动结果的年度汇总，并通过第 95 条所述的电子系统提供给其他主管机构。

5. 主管机构为保护公共卫生利益， 对于具有不可接受的风险或虚假器械， 可没收、 销毁等。

6. 根据第 1 段所述的目的执行每次核查后， 主管机构应起草涉及现有法规及技术要求符合

性的核查发现的相关报告。报告应给出必要的纠正措施。

7. 执行检查的主管机构应将本条第 6 段所述的报告内容传达给经济运营商检查对象。在最终检查报告通过前，主管机构应给予该经济运营商提交意见的机会。该最终检查报告应输入第 95 条规定的电子系统。

8. 成员国应审查并评估其市场核查活动的运行情况。此类审查和评估应至少每四年进行一次，并将结果告知其他成员国和委员会。各成员国应通过第 95 条所所述的电子系统向公众公布结果总结。

9. 成员国主管机构应协调其市场监管活动，彼此合作，互相分享，并与委员会分享结果，以便在所有成员国协调一致保持高水平的市场监管。

在适当情况下，成员国主管机构应同意工作共享、共同进行市场监管，共享专业化。

10. 若超过一个成员国的主管机构负责市场监管和外部边界控制，这些机构应通过分享其作用和职能相关的信息而相互合作。

11. 在适当情况下，成员国主管机构应与第三国主管机构合作，以便交流信息和提供技术支持，促进有关市场监管的活动。

第 89 条

对涉嫌不可接受风险或其他不合规的器械的评估

若成员国的主管机构根据警戒或市场监管活动或其他途径获得的数据，怀疑器械：

(a) 可能对患者、使用者或其他人的健康和安全、或对保障公众健康的其他方面带来不可接受的风险，或者

(b) 该器械不符合本法规的要求，

则主管机构应就相关器械进行评估，评估内容涵盖本法规中关于器械施加的风险或其他不符合性的相关的所有要求。相关经济运营商应与主管机构合作。

第 90 条

对健康和安全带来不可接受风险的器械的处理程序

1. 当根据第 89 条执行评估后，倘若主管机构发现该器械可能对患者、使用者或其他人的健康和安全、或对保障公众健康的其他方面带来不可接受的风险，则主管机构应立即要求相关器械的制造商、其授权代表和其他所有相关经济运营商采取一切适当且合理的纠正措施，使该器械符合本法规与器械施加风险相关的要求，并以与风险性质相对应的方式来限制该器械在市场上的流通，或使该器械的流通遵守特定要求，或将该器械撤出市场，或在合理期限内召回该器械，该期限应予以明确确定，并传达给相关经济运营商。

2. 主管机构应通过第 95 条中所述的电子系统，立即向委员会、其他成员国，以及当根据第 51 条的规定签发相关器械证书的情况下，公告机构告知评估结果、以及其要求经济运营商应采取的相关措施。

3. 对于已投放至整个欧盟市场的所有相关器械，第 1 段所述的经济运营商应立即采取所有适当的纠正措施。

4. 倘若第 1 段所述的经济运营商未于第 1 段中规定的期限内采取充分的纠正措施，则主管机构应采取一切适当措施，禁止或限制该器械在本国市场上的流通，将该器械撤出市场，或将其召回。

该主管机构应通过第 95 条中所述的电子系统，立即向委员会、其他成员国和本条第 2 段所述的公告机构告知此类纠正措施。

5. 第 4 段所述的通知应包括所有可用的详细信息，特别是识别和追踪不合规器械所必需的数据、器械来源、器械不合规项的性质和原因以及相关风险、国家所采取的措施的性质和持续时间、以及相关经济运营商提出的论点。

6. 成员国（发起流程的成员国除外）应通过第 95 条中所述的电子系统，立即通知委员会和其他成员国，处置相关器械不合规项以及针对相关器械所采取的纠正措施的任何额外相关信息。倘若不同意所通知成员国采取的措施，则该成员国应通过第 95 条中所述的电子系统，立即向委员会和其他成员国通知其反对意见。

在收到第 4 段中所述的通知后的两个月内，倘若成员国或委员会均未对某一成员国所采取的任何措施提出反对意见，则此类措施应视为合理。

7. 在这种情况下，则所有成员国应立即对相关器械采取相应的适当限制性或禁止性措施，包括撤回、召回或限制其在本国市场上的流通。

第 91 条

在欧盟层面评估国家措施的流程

1. 在收到第 90（4）条所指的通知的两个月内，倘若某一成员国对另一成员国采取的措施提出反对意见，或委员会认为该措施违反欧盟法律，则在咨询相关主管机构和相关经济运营商（如有必要）后，委员会应评估该国家措施。基于该评估结果，委员会可通过实施细则来决定该国家措施是否合理。应按照第 107（3）条中述及的审查流程来通过这些实施细则。

2. 若委员会认为本条第 1 段所述的该国家措施合理，则应适用第 90（7）条第二子段。若委员会认为该国家措施不合理，则有关成员国应撤销该措施。

在收到第 90（4）条所述的通知的八个月内，倘若委员会未按照本条第 1 段采纳一项决定，则该国家措施应视为合理。

3. 若某一成员国或委员会认为，由于某个器械对健康和安全造成的风险无法通过相关成员国采取的措施得到圆满缓解，则委员会可在某一成员国的要求下或自行决定通过实施细则采取必要且正当合理的措施，以保障健康和安全，该措施包括限制或禁止将相关器械投放市场或投入使用。应按照第 107（3）条中述及的审查流程来通过这些实施细则。

第 92 条

其他不合规项

1. 当根据第 89 条执行评估后，倘若某一成员国的主管机构发现某个器械不符合本法规规定的要求，但不会对患者、使用者或其他人的健康和安全、或对保障公众健康的其他方面带来不可接受的风险，则该成员国可要求相关经济运营商在合理期限内解决相关不合规项，该期限应予以明确确定，并传达给经济运营商，且与不符合性相对应。

2. 倘若经济运营商未于本条第 1 段所述的期限内解决该不合规项，则相关成员国应及时采取一切适当措施，限制或禁止该产品在市场上流通，或确保其从市场上召回或撤回。该成员国应通过第 95 条所述的电子系统，立即向委员会和其他成员国通知此类措施。

3. 委员会可通过实施细则指定由主管机构采取适当措施，消除给定类型的不合规项，以确保统一适用本条规定。应按照第 107（3）条中述及的审查规程通过这些实施细则。

第 93 条

预防性健康保护措施

1. 当执行一项评估，且评估表明某个器械或特定的器械类别或分组存在潜在的风险，倘若成员国认为，为保障患者、使用者或其他个人的健康和安全或公众健康的其他方面，应当禁止或限制该器械或该器械特定类别或分组在市场上流通或投入使用，或使其符合特定要求，或将此类器械或器械类别或分组从市场上撤出或召回，该成员国可采取一切必要且合理的措施。

2. 第 1 段所述的成员国应通过第 95 条所述的电子系统，立即告知委员会和其他所有成员国，并给出其决定的理由。

3. 委员会应与 MDCG 或有关经济运营商 （必要时） 磋商，对国家采取的措施进行评估。委员会可通过实施细则来决定该国家措施是否合理。倘若委员会未于接到通知的六个月内做出决定，则该国家措施应视为合理。应按照第 107（3）条中述及的审查流程来通过这些实施细则。

4. 倘若本条第 3 段所述的评估表明，为保障患者、使用者或其他个人的健康和安全或公众健康的其他方面，应禁止或限制某个器械或特定的器械类别或分组在市场上流通或投入使用，或应使其符合特定要求，或应将此类器械或器械类别或分组从市场上撤出或从各成员国中召回，委员会可通过实施细则，以执行必要且适当合理的措施。这些实施细则应根据第 107（3）条所述的审查流程来审批。

第 94 条

良好行政管理规定实践

1. 对于成员国主管机构根据第 90 条至 93 条的规定采取的任何措施，应说明其所依据的确切理由。倘若此等措施针对某个特定的经济运营商，则主管机构应立即通知措施相关经济运营商，同时向经济运营商告知依据法律或相关成员国的行政管理规定

实践的补救措施、以及此类补救措施的期限。倘若该项措施普遍适用，则应进行适当范围内公布。

2. 除因对人类健康或安全带来不可接受的风险而必需采取即时行动情况之外，在采取任何措施之前，应给予相关经济运营商机会，在明确规定的适当期限内向主管机构提交意见书。倘若在经济运营商没有机会提交第 1 子段所述的文件的情况下，已经采取了措施，则应给予该经济运营商机会，以尽快提交意见书，之后应立即对已采取的措施进行审查。

3. 一旦经济运营商证明其已采用更为有效的纠正措施，且该器械已符合本法规的要求，则应立即撤回或修订已采取的措施。

4. 倘若根据第 90 条至第 93 条采取的措施涉及到公告机构参与符合性评估的器械，则主管机构应通过第 95 条所述的电子系统，向相关公告机构和负责该公告机构的当局通知所采取的措施。

第 95 条

市场监管中的电子系统

1. 委员会应与成员国合作，建立并管理一套电子系统，以整理和处理以下信息：

(a) 第 88（4）条中所述的监管活动的结果总结；

(b) 第 88（7）条中所述的最终检验报告；

(c) 第 90（2）、（4）和（ 6）条中所述的、可能对健康和安全带来不可接受风险的相关器械的信息；

(d) 第 92（2）条中所述的产品不合规项的相关信息；

(e) 第 93（2）条中所述的预防性保健措施的相关信息；

(f) 第 88（8）条中所述的成员国市场监管活动的审查和评估结果总结。

2. 本条第 1 段中所所述的信息应通过电子系统及时传送给所有相关主管机构，如适用，也可传送至根据第 51 条签发相关器械证书的公告机构，并向成员国和委员会公开。

3. 当此等行为可能损害成员国之间的市场监管活动与合作时，成员国之间的信息交换不得对外公开。

第 VIII 章

成员国、医疗器械协调小组、欧盟参考实验室、器械注册机构间的合作

第 96 条

主管机构

成员国应指定主管机构或负责本法规的实施的官方机构。成员国应根据本法规的要求向其机构授予所需的权力、资源、设备和知识，以便适当履行其任务。成员国应向委员会告知主管机构的名称和联系方式，再由委员会公布主管机构名单。

第 97 条

合作

1. 成员国的主管机构应相互合作，并与委员会合作，委员会应提供组织交流的必要信

息，使本法规统一适用。

2. 成员国应在委员会的支持下，在适当时候在国际层面进行倡议，以确保监管机构在医疗器械领域开展合作。

第 98 条

医疗器械协调小组

根据本欧盟第 2017/745 号法规第 103 条和第 107 条中确定的条件和方式所设立的医疗器械协调小组（MDCG）应在欧盟第 2017/745 号法规第 104 条中规定的委员会的支持下履行根据本法规及欧盟第 2017/745 号法规指派给其任务。

第 99 条

MDCG 的任务

根据本法规，MDCG 的工作任务如下：

(a) 根据第 IV 章规定，帮助评估申请人符合性评估机构和公告机构；

(b) 根据第 45 条确立的关于公告机构的协调小组事宜，向委员会提供意见；

(c) 帮助制定旨在确保此法规有效和协调实施的指南，特别是关于公告机构的指定和监管、通用安全与性能要求的应用、由制造商进行的性能评估、由公告机构进行的评估和警戒活动；

(d) 帮助持续监控技术进展和评估本法规中及欧盟第 2017/745 号法规中的通用安全与性能要求是否合适，以确保器械的安全与性能，从而有助于确认是否需要修订本法规附录 I；

(e) 帮助制定器械标准和 CS；

(f) 协助成员国主管机构开展协调活动，特别是器械的分类和法规现状、性能研究、警戒和市场监管等领域，包括根据第 88 条规定，以欧盟市场监管的效率和协调为目标，制定和维护欧盟市场监管计划的框架；

(g) 在本法规实施的任何相关问题评估中，主动或在委员会的要求下，提供意见；

(h) 帮助协调成员国的器械相关的行政法规实施。

第 100 条

欧盟参考实验室

1. 对于特定器械，或一类或一组器械，或与同类或同组器械相关的特定风险，委员会可通过实施细则，指定单个或多个欧盟参考实验室（以下简称“EU 参考实验室”），以满足第 4 段所提出的标准。委员会仅为已提交指定申请的成员国或委员会联合研究中心指定 EU 参考实验室。

2. 在其指定范围内，如适当，欧盟参考实验室的工作任务如下：

(a) 验证制造商所声称的性能，以及 D 类器械与适用的 CS（如有）的符合性，或如第 48（3）条的第三小段规定的，由制造商选择的其他方案，以确保同一水平的安全性和性能相当；

(b) 根据附录 X 第 4.12 节和附录 XI 第 5.1 节规定，对制造的 D 类器械样品或 D 类器械批次进行适当测试；

(c) 向委员会、MDCG 、成员国和公告机构提供关于实施本法规的科学和技术援助；

(d) 就特定器械、一类或一组器械相关的现有技术水平提供科学建议；

(e) 与国家主管机构协商后，建立和管理国家参考实验室网络，并公布参与国家参考实验室的成员名单及各自任务；

(f) 帮助制定适用于符合性评估流程和市场监管的适当测试和分析方法；

(g) 与公告机构合作，制定符合性评估流程性能的最佳方案；

(h) 就合适的参考物质和较高计量等级的参考测量流程提出建议；

(i) 帮助制定 CS 和国际标准；

(j) 根据本法规对公告机构的咨询提供科学性意见，并考虑到国家保密条款规定，通过电子方式公布。

3. 应某一成员国的请求，委员会也可指定欧盟参考实验室，该成员国希望通过此实验室，确保有能力验证制造商所声称的性能，以及 C 类器械适用的 CS（如有）的符合性，或由制造商选择的其他方案，以确保同一水平安全与性能相当。

4. 欧盟参考实验室应满足以下标准：

(a) 拥有足够和有适当资质的工作人员，其具有指定体外诊断医疗器械领域拥有足够的知识和经验；

(b) 拥有必要的设备和参考材料来执行分配的任务；

(c) 具有必要的国际标准和最佳实践知识；

(d) 具有适当的行政组织和架构；

(e) 确保其工作人员在执行任务时遵守信息和所获数据的保密性规定；

(f) 以公共利益为重，独立运营；

(g) 确保其工作人员在体外诊断医疗器械产业中无任何可能影响其公正性的财务或其他利益，声明其在体外诊断医疗器械产业中的任何直接或间接利益，并在发生相关变化时更新声明。

5. 欧盟参考实验室应形成一个网络，以根据测试和评估协调其工作方法。该协调涉及到：

(a) 采用协调方法、流程和过程；

(b) 同意使用相同的参考物质、通用测试样品和血清转换盘；

(c) 制定通用评估和解释标准；

(d) 采用通用测试方案，并用标准化协调一致的评估方法评估测试结果；

(e) 采用标准化协调一致的测试报告；

(f) 开发、应用和维护同行评审系统；

(g) 定期组织质量评估测试（包括对质量和测试结果可比性的相互检查）；

(h) 赞同联合准则在、指令、流程指令或标准操作流程；

(i) 协调引入新技术的测试方法，并遵循新的或经修订的 CS；

(j) 按照成员国或委员会的要求， 基于比较测试结果或通过进一步研究重新评估现有技术水平；

6. 欧盟参考实验室可获得欧盟财政资助。

鉴于保护健康和安全、 支持创新和成本效益之目的，委员会可通过实施细则，规定提供给欧盟参考实验室的财政资助方式和数额。应按照第 107（3）条中述及的审查规程来通过这些实施细则。

7. 公告机构或成员国要求获取欧盟参考实验室的科学或技术援助或科学意见时， 其需要支付因实验室按照一系列规定的透明条款执行所要求的任务所产生的全部或部分费用。

8. 委员会应通过实施细则规定：

(a) 便于应用本条第 2 段规定的细则和确保遵守本条第 4 段所述标准的细则。

(b) 鉴于保护人体健康和安全保护、 支持创新和成本效益目的， 确定本条第 7 段所述的费用结构和水平， 该费用由欧盟参考实验室根据本法规规定， 就公告机构和成员国的咨询提供科学性意见的事宜收取。

应采用符合第 107(3) 条中所述的检查流程的措施执行实施这些规则。

9. 欧盟参考实验室应受委员会管控，包括现场访问和审计， 以验证其是否符合本法规要求。若管控过程中，发现实验室不符合指定要求，委员会应通过实施细则，采取适当措施，包括限制、暂停或撤销参考实验室 委任 。

10. 欧盟第 2017/745 号法规第 107（1）条中的规定应适用于欧盟参考实验室的工作人员。

第 101 条

器械注册机构和数据库

委员会和成员国应采取所有适当措施，鼓励建立特定器械类型的登记表和数据库，以制定通用原则，收集可比较信息。这种登记表和数据库有助于器械长期安全性和性能的独立评估。

第 IX 章

机密性、数据保护、资金来源及处罚

第 102 条

机密性

1. 除非本法规另有规定，且不影响成员国现有国家保密条款和惯例，否则，所有适用本法规的成员应遵守在执行任务时所获得的信息和数据的保密性规定，以保护以下内容：

(a) 符合第 103 条规定的个人数据；

(b) 自然人或法人的商业机密信息和商业秘密， 包括知识产权， 符合公共利益的披露除外；

(c) 本法规的有效执行，特别是以检查、调查或审查为目的。

2. 在不影响第 1 段规定的情况下，未经发起机构事先同意，不得披露主管机构之间、主管机构与委员会之间处于保密状态的交流信息。

3. 第 1 和 2 段不得影响委员会、成员国和公告机构在信息交流和警戒信息传播方面的权利和义务，也不得影响根据刑法提供信息的有关人员的义务。

4. 委员会和成员国可与签订双边或多边保密协议的第三方监管机构交流机密信息。

第 103 条

数据保护

1. 成员国应适用第 95/46/EC 指令，根据本法规规定在成员国内处理个人数据。

2. EC 45/2001 号法规应适用于委员会按照本法规进行的个人数据处理。

第 104 条

收费

1. 只要费用水平透明，且基于成本回收原则，则本规例将不妨碍 成员国 就本法规所规定活动所征收的费用。

2. 成员国应在采纳费用和收费水平前至少三个月通知委员会和其他成员国。费用构成和收费水平应按要求公开。

第 105 条

指定公告机构和监控活动的资金

与联合评估活动有关的费用应由委员会承担。

委员会应通过施行法案规定可回收成本的比例和结构以及其他必要的实施细则。应按照第 107（3）条中述及的审查流程来通过这些实施细则。

第 106 条

处罚

各成员国应制定适用于违反本法规规定的处罚规则， 并应采取一切必要措施， 确保这些规定的实施。 规定的惩罚应当有效、 适度和具有劝阻性。 成员国应在 2022 年 2 月 25 日前就这些规则和措施通知委员会，且应及时通知，以免影响任何后续修订。

第 **X** 章

最终条款

第 107 条

委员程序

1. 委员会由欧盟第 2017/745 号法规第 114 条成立的医疗器械委员会（应为欧盟第 182/2011 号法规含义中的委员会）予以协助。

2. 若该段引用了参考资料，则应适用欧盟第 182/2011 号法规第 4 条。

3. 若该段引用了参考资料，则应适用欧盟第 182/2011 号法规第 5 条。

若委员不发表意见，则委员会不得通过实施细则草案，且应适用欧盟第 182/2011 号法规第 5(4)条中的第 3 子段。

4. 参考本段时，同样适用欧盟第 182/2011 号法规第 8 条及第 4 或 5 条（如适用）。

第 108 条

授权

1. 根据本条款规定，授予委员会实施授权的权力。

2. 第 10、17（4）、24（10）、51（6）和 66（8）条所述采取授权行为的权力应自 2017 年 5 月 25 日起授予委员会，其有效期为 5 年。委员会应在 5 年有效期结束前至少 9 个月就所授权力起草一份报告。默认转授权力应延长相同的期限，除非欧洲议会或者理事会在各期限结束前三个月反对此类延时。

3. 第 10、17（4）、24（10）、51（6）和 66（8）条所述授权可由欧洲议会或理事会随时撤销。撤销决定将终止该决定中指定的权力授予。其生效日期应当为欧盟官方公告发表该决定后或者在决定规定的一个后续日期。它对已生效的授权法案效力无任何影响。

4. 采取授权行为之前，委员会应根据 2016 年 4 月 13 日《改善的立法机构间协议》所规定的原则，咨询各成员国指定的专家。

5. 在采用授权法案之后，委员会应同时通知欧洲议会和理事会。

6. 按照第 10（4）、17（4）、24（10）、51（6）和 66（8）条通过的授权法案只有在欧洲议会或者理事会在收到该法案通知后三个月未向欧洲议会和理事会提出异议，或者在此期限期满前，欧洲议会和理事会都通知委员会表示自己不反对时方可生效。欧洲议会或者理事会可主动将此期限延长三个月。

第 109 条

不同授权的单独授权行为

委员会应就根据本法规授予其每项权力采取单独的授权行为。

第 110 条

过渡性条款

1. 自 2022 年 5 月 26 日起，公告机构根据第 98/79/EC 号指令发布的任何通知将失效。

2. 在 2017 年 5 月 25 日之前，公告机构根据第 98/79/EC 号指令签发的证书在证书所示期限到期前应继续有效，但是根据第 98/79/EC 号指令附录 VI 签发的证书应在 2024 年 5 月 27 日之前失效。

自 2024 年 5 月 25 日起，公告机构根据第 98/79/EC 号指令签发的证书应在 2024 年 5

月 27 日之前失效。

3. 根据本法规第 5 条规定，仅具有根据第 98/79/EC 号指令规定颁发器械证书并经过本条第 2 段检验有效的器械可投放市场或投入使用，前提是自本法规适用之日起，其继续遵守且在设计和预期的目的上无显著变化。但是，本法规有关市场后监察、市场监察、警戒、经济运营商及器械注册的规定须适用并取代该指令的相应要求。

在不影响第 IV 章和本条第 1 段规定的前提下， 颁发第 1 段中的所述的证书的公告机构应继续负责适当监管有关其认证器械的所有适用要求。

4. 在 2022 年 5 月 26 日之前，根据第 98/79/EC 号指令依法投放市场的器械及自 2022 年 5 月 26 日起投放市场并具有本条第 2 段中所述的证书的器械在 2025 年 5 月 27 日之前可继续投放市场或投入使用 。

5. 通过豁免第 98/79/EC 号指令，符合本法规的器械可在 2022 年 5 月 26 日之前投放市场。

6. 通过豁免第 98/79/EC 号指令，可在 2022 年 5 月 26 日前指定并通知符合该法规的符合性评估机构。根据本法规指定并通知的公告机构可在 2022 年 5 月 26 日前，采用其规定的符合性评估流程并按照本法规签发证书。

7. 对于根据第 48（3）和（ 4）条所述流程进行评估的器械，本条第 5 段适用，条件是已委派必要的 MDCG 、专家小组和欧盟参考实验室。

8. 通过豁免第 98/79/EC 号指令第 10 条和第 12（1）条（ a）和（ b）点规定的方式，在在自第 113（3）第（ f）点日期起 18 月后所述日期中较晚日，符合本法规第 27（3）、28（1）和 51（5）条的制造商、授权代表、进口商和公告机构应被视为符合成员国根据第 2010/227/EU 号决议规定的第 98/79/EC 号指令第 10 条及第 12（ 1）条（ a）和（ b）点通过的法律法规。

9. 成员国主管机构根据第 98/79/EC 号指令第 9（12）条的授权在授权所注明期限内应继续有效。

10. 在委员会根据第 24（ 2）条指定 UDI 分配实体前， GS1、HIBCC 和 ICCBBA 应被视为指定的 UDI 分配实体。

第 111 条

评估

在 2027 年 5 月 27 日之前，委员会应对本法规的适用范围进行评估，并就实现法规目标的进展制定评估报告，包括对实施本法规所需资源的评估。应特别注意，经济运营商、卫生机构和卫生专业人员可根据第 24 条规定通过 UDI 对存储的器械进行追溯。评估还应包括对第 4 条履行情况的审查。

第 112 条

废除

在不影响本法规第 110（3）和（ 4）条规定和第 98/79/EC 号指令下有关成员国和制造商警戒责任和有关制造商使文件可用的责任下，本指令自 2022 年 5 月 26 日起废除，但以下情况除外：

（a）自第 113（2）和 113（3）条（（f）点所述日期中较晚日期起废除第 98/79/EC 号指令第

11 条、第 12（1）条（ c）点及第 12（2）和（ 3）条，以及在相应附录中规定的警戒责任和性能研究。

（b）本法规第 113（2）和 13（2）条（d）点所述日期中较晚日期后 18 个月起废除的第 98/79/EC 号指令第 10 条、第 12（1）条（ a）和（ b）点和相关器械和经济运营商注册和相应附录中规定的认证通知。

有关本法规第 110（3）和（ 4）条中所述的器械，第 98/79/EC 号指令应继续适用本法规适用的范围至 2025 年 5 月 27 日止

自本法规第 113（2）和 113（3）条（d）点所述日期中较晚日期起废除在实施第 90/385/EEC 、93/42/EEC 和 98/79/EC 号指令时采用的委员会第 2010/227/EU 号决议。

参考废除指令应理解为参考本法规，并应按照附录 XV 中所列对比表进行阅览。

第 113 条

生效与应用日期

1. 本法规应在《欧盟官方公报》上公布后第 20 天生效。
2. 本法规应自 2022 年 5 月 26 日起适用 。
3. 通过豁免第 2 段规定的方式：

(a) 第 27（3）和 51（5）条应自 2023 年 11 月 27 日起适用；

(b) 第 31 至 46 条和第 96 条应自 2017 年 11 月 27 日起适用。 根据第 31 至 46 条规定自 2022 年 5 月 26 日起所产生的公告机构义务应仅适用于根据 34 条提交指定申请的机构。

(c) 第 97 条应自 2018 年 5 月 26 日起适用

(d) 第 100 条应自 2020 年 11 月 26 日起适用

(e) 对于 D 类器械，第 24（4）条应自 2023 年 5 月 26 日起适用。对于 B 类和 C 类器械， 第 24（4）条应自 2025 年 5 月 26 日起适用。 对于 A 类器械， 第 22(4) 条应自 2027 年 5 月 26 日起适用。

(f) 在不影响欧盟法规 2017/745 第 34 条规定的委员会义务的情况下， 由于在起草该法规第 34（1）条所述计划时无法合理预见的情况除外。 在 Eudamed 自 2022 年 5 月 26 日起未能充分生效时， 则相关 Eudamed 的责任和要求应其应自该法规第 34（3）条所述通知发布后 6 个月起适用。上述段落中所述的条款为：

—第 26 条

—第 28 条

—第 29 条

—第 36（2）条第 2 段

—第 38（10）条

—第 39（2）条

—第 40（12）条第 2 段

—第 42（7）条（ d）和（ e）点

—第 49（2）条

—第 50（1）条

—第 66 至 73 条

—第 74 条第 1 至 13 段

—第 75 至 77 条

—第 81（2）条

—第 82 和 83 条

—第 84（5）、（7）条和第（84）8 条第 3 段

—第 85 条

—第 88（4）、（7）和（8）条

—第 90（2）和（4）条

—第 92（2）条最后一句

—第 94（4）条

—第 110（3）条第 1 段第 2 句

在 EUDAMED 充分发挥作用之前，为实现本点第 1 段条款规定的有关信息交换包括尤其是相关性能研究、警戒报告和器械和经济运营商和证书通知的信息义务，98/79/EC 指令相应条款应继续适用。

（g） 第 74 条规定的程序应在不影响第 74（14）条规定前提下，自 2027 年 5 月 26 日起适用。

（h） 第 110（10）条应自 2019 年 5 月 26 日起适用

本法规应整体具有约束力，并直接适用于所有成员国。

2017 年 4 月 5 日于斯特拉斯堡签署

签署人：

欧洲议会	理事会
会长	会长
A. TAJANI	I. BORG

附录

附录 I

通用安全与性能要求

第 I 章

一般要求

1. 器械应具备制造商预期的性能，并确保其设计和生产在正常使用条件下适用于其预期用途。 器械应安全有效， 不得对患者的临床症状或安全、 或使用者或其他人员 （如适用）的安全和健康造成损害，器械使用风险与其对患者的益处相比，应在可接受范围内，并应在较高水平上维护健康和安全，并考虑到具备公认的现有技术水平。

2 本附录要求尽可能降低风险的要求是指尽可能降低风险的同时不会对风险效益比产生不利影响。

3 制造商应建立、实施、记录和维护风险管理体系。

风险管理在器械整个生命周期中为连续迭代过程，需定期更新系统进行风险管理。制造商应：

(a) 制定并记录各器械的风险管理计划；

(b) 识别和分析与各器械相关的已知和可预见的危害；

(c) 评估在预期使用时及在可预见的使用不当时产生的相关风险；

(d) 根据第 4 节（ c）点所述要求消除或控制这些风险；

(e) 评估来自生产阶段以及， 特别是来自上市后监管体系中的危害及其发生频率等信息可能带来的影响，因此，需 评估与之相关的风险，以及总体风险，利益 - 风险比和风险可接受性 ；

(f) 根据第（ e）点所述信息影响的评估，必要时根据第 4 节的要求修改控制措施。

4. 制造商就器械的设计和制造所采取的风险控制措施应符合安全原则，并考虑到公认的现有技术水平。为降低风险，制造商应对风险进行管理，使各危害相关的剩余风险及总剩余风险控制在可接受范围内。在选择最合适的解决方案时，制造商应按照以下优先顺序考虑：

(a) 通过安全的设计和生产尽可能消除或减少风险；

(b) 若适合，采取适当保护措施，关于无法消除的风险，包含必要时的报警；且

(c) 提供安全信息（警戒 /预防措施 /禁忌），并在适当情况下向使用者提供培训。

制造商应将剩余风险告知使用者。

5. 在消除或减少使用不当相关风险时，制造商应：

(a) 尽量降低因器械人体工程学特点及其预期使用环境所造成的风险 （针对患者安全而设计），以及

(b) 考虑技术知识、经验、教育、培训和使用环境，以及预期使用者医疗及身体条件（如适用） （针对非专业、专业、残疾或其他使用者而设计） 。

6. 若器械在正常使用环境中使用并根据制造商的指示进行适当维护保养，则在制造商声称的使用期限内，器械的特性和性能不得对患者、使用者或其他人员（如适用）的健康或安全造成损害。

7. 器械的设计、制造和包装应确保在根据制造商提供的说明和信息进行运输和储存期时（如温度和湿度的波动），不会对器械的预期用途的特性和性能造成不利影响。

8. 与正常使用条件下器械预期性能对患者和/或使用者产生的潜在益处相比，所有已知和可预见的风险及任何不良影响应最小化并控制在可接受范围内。

第 II 章

性能、设计和生产相关要求

9. 性能特性

9.1. 器械的设计和生产应确保其适用于制造商规定的第 2 条第（ 2）点条所述目的，其性能具备预期达到的公认的现有技术水平。器械应具备制造商所声称的性能，特别是以下性能（如适用）：

(a) 分析性能，如分析灵敏度、分析特异性、真实性（偏差）、精密度（重复性和重现性）、准确性（真实性和精密度的结果）、检出限和定量限、测量范围、线性、阳性判断值，包括确定样本收集和处理适用标准及控制已知相关内源和外源干扰，交叉反应；和

(b) 临床性能，如诊断灵敏度、诊断特异性、阳性预测值、阴性预测值、概率比、正常和受影响人群的预期值。

9.2. 器械的性能特点应在制造商声称的使用期限内保持有效性。

9.3. 若器械性能取决于校准品和/或质控品的使用，则应通过合适的参考测量流程和/或较高计量等级的合适参考品确保校准品和/或质控品赋值的计量溯源性。如适用，应溯源至有证的参考物质或参考测量流程来确保校准品和/或质控品赋值的计量溯源性。

9.4. 器械在正常条件下用于预期用途时，应特别检查可能受到影响的特性和性能：

(a) 用于自我监测的器械，由外行验证的性能；

(b) 用于床旁检测的器械，在相关环境中验证的性能（如患者家、急救单位、救护车）。

10. 化学、物理和生物学特性

10.1. 器械的设计和生产应确保其符合第 I 章“ 一般要求 ”中所述性能要求。

考虑到器械的预期用途，应特别留意由于所用材料和样本间、待检测分析物和标记物（例如生物组织、细胞、体液和微生物）间的物理性和/或化学性配伍禁忌而引起的分析性能降低可能性。

10.2. 器械的设计、生产和包装应尽可能降低污染物和残留物对患者造成的风险，同时考虑

到器械预期用途以及参与器械运输、 存储和使用的人员。 应特别注意暴露于这些污染物和残留物的组织以及暴露的持续时间和频率。

10.3 根据欧洲议会和理事会第 1272/2008 号法规（[1]）附件 VI 第 3 部分，，器械的设计和生产应尽可能合理降低器械可能释放物质或颗粒物所造成的风险，包括磨屑、降解产物、加工残留物。应特别留意致癌、致突变或生殖毒性物质（ 'CMR'），并特别留意内分泌干扰特性物质，有科学证据证明该类物质可能严重影响人类健康，根据欧洲议会和理事会第 1907/2006 号法规（[2]）第 59 条所载流程进行鉴别。

10.4 必须合理设计及生产器械，以尽量降低因物质意外进入器械而造成的风险，并且考虑到器械及其预期使用环境的性质。

11. 感染及微生物污染

11.1. 器械和其制造工艺的设计应尽可能消除或降低对使用者、或视情况对他人的感染可能性。设计应：

(a) 使用便捷安全；

(b) 尽可能降低器械的微生物泄漏和 /或使用过程中的微生物暴露；

并且，必要时

(c) 防止器械在使用过程中的微生物污染， 当为样本容器时， 防止对样本造成的污染。

11.2 标识为无菌或含特定微生物状态的器械设计、制造和包装应确保在制造商指定的运输和存储状态下保持无菌条件或微生物状态；直至在使用时打开包装，除非保持其无菌条件或微生物状态的包装已遭损坏。

11.3 标识为无菌的器械应采用适当的验证方法验证其加工、制造、包装、灭菌流程。

11.4 预期灭菌的器械应采用适当且可控条件和设备进行生产和包装。

11.5 非无菌器械的包装系统应保持产品的完整性和清洁度，并且若器械在使用前将要被灭菌，尽量减少微生物污染风险；包装系统应适当考虑到制造商指定的灭菌方法。

11.6 器械标识除带有灭菌器械的指示符号外，还应可区别市场上相同或相似器械的灭菌和非灭菌状态。

12. 包含生物源材料的器械

当器械包括来源于动物、人类或微生物的组织、细胞和物质时，则来源选择、该来源组织、细胞和物质的处理、保存、测试和处理以及控制流程应保护使用者或他人安全。

([1]) 2008 年 12 月 16 日欧洲议会和理事会第 1272/2008 号法规关于物质和混合物的分类、标签和包装附录 VI 第 3 部分规定，该法规修订和废止第 67/548/EEC 号指令第 1999/45/EC 号指令，修订欧盟委员会第 1907/2006 号法规（ OJ L 353, 31.12.2008, p. 1.）

([2]) 2006 年 12 月 18 日欧洲欧洲议会和理事会第 1907/2006 号关于化学品注册、评估、授权和限制（研究）法规（ OJ L 136， 29.5.2007， p.3）

尤其是，在制造工艺期间，需执行对采用的消除或灭活方法的验证，解决与微生物和其他传染物质有关的安全问题。若微生物和其他传染因子的活性是器械预期用途必不可少的一部分，或者该消除或灭活过程可能降低器械性能，则该条将不适用于此类器械。

13. 器械构造及其与环境之间的相互作用

13.1. 若器械预定与其他器械或设备一起配合使用，必须保证整体（包括连接系统）具有安全性，同时不得改变此器械的特定性能。任何有关此类配合使用的限制应在标签和/或使用说明书上标明。

13.2. 应采用适当方式设计和制造器械，确保尽可能地避免或减少：

(a) 与器械物理特征有关的伤害风险，包含体积/压力比、尺寸和人体工程学特征（如适用）；

(b) 与可预见的外部影响或环境条件相关的风险，例如磁场、外部电场和电磁效应、静电放电、诊断或治疗流程的辐射、压力、湿度、温度、压力变化和压力加速或者无线电信号干扰；

(c) 与该器械使用相关的风险，当其在正常使用条件下接触的材料、液体和物质，包括气体。

(d) 与软件和其操作及相互作用的 IT 环境间可能的负面交互作用相关的风险。

(e) 物质意外进入器械的风险；

(f) 样本非正确鉴别的风险以及产生错误结果的风险，例如，由于与器械一同使用以进行预期测试或测定的样本容器、活动部件和/或附件的颜色和/或数字和/或字符编码混淆、导致的错误结果；

(g) 与其他器械的任何可预见干扰风险。

13.3. 必须适当地设计和制造器械，确保在正常使用期间和单一故障情形下尽量减少火灾或爆炸风险。应特别注意其预期用途包括暴露于或与易燃或易爆物质或可能引起燃烧的物质结合使用的器械。

13.4. 器械的设计和制造应确保可安全且有效地进行调整、校准和维护。

13.5. 用于与其他器械或产品协同操作的器械设计和制造应确保其互通性和兼容性可靠且安全。

13.6. 器械的设计和制造应便于使用者或他人安全处置器械和/或相关废物。为此，制造商应检验并测试流程和措施，以便器械可使用后安全处置。这些流程和措施应在使用说明书中说明。

13.7 计量、监控或显示比例（包括颜色变化和其他视觉指示器）的设计和制造应符合人体工程学原理，同时考虑到器械预期用途、使用者以及预期使用环境条件。

14. 具有测定功能的器械

14.1. 考虑到器械预期用途，带初级分析测定功能的器械的设计和制造应能够提供符合附录 I 第 9.1 节(a)点的适当分析性能。

14.2. 具有测定功能的器械，并以法定单位表示测量的结果必须符合理事会第 80/181/EEC 号指令（ [1]）中的规定。

15. 辐射防护

15.1. 器械的设计、制造和包装应尽量减少对使用者或者他人的辐射（有意、无意、杂散或散射），并以与预期目的相容的方式，同时不限制其用于诊断目的适当规定水平的应用。

15.2. 当器械预期会发出有害或可能有害、电离和 /或非电离辐射时，应尽可能：

(a) 其设计和制造应确保所发出辐射的特性和量可控和 /或可调整；

(b) 配备针对此类辐射的可视显示器和 /或声音警告

15.3. 发出有害或潜在危险辐射的器械使用说明书应包括发出辐射的性质、 保护使用者的方法，尽可能避免误用及减少安装所造成的风险的详细信息。 应详细说明验收、 性能测试、验收标准以及维护程序的有关信息。

16. 可编程电子系统 —— 包含可编程电子系统的器械与本身就是器械的软件

16.1. 包含可编程电子系统 （包括软件） 的器械或者自身为器械的软件， 其设计应根据其预期用途确保相应可重复性、 可靠性和性能。 在单一故障条件下， 应采取适当手段以尽可能消除或降低由此造成的风险或性能损害。

16.2. 针对包含软件的器械或自身为器械的软件， 应根据现有技术开发和制造软件， 同时考虑开发生命周期、风险管理的原则，包括信息安全、验证和确认。

16.3. 本节所指软件当与移动计算平台结合使用时， 其设计和制作应考虑移动平台的特定特征（如屏幕的大小和对比度）以及与其用途相关的外部因素（环境变化，如光照或噪声水平）。

16.4. 制造商应规定有关硬件、 IT 网络特性和 IT 安全措施的最低要求，包括防止未授权访问、按预期运行软件的必要条件。

17. 有源器械和与其连接的器械

17.1 对于有源器械和与其连接的器械， 在发生单一故障情况时， 应采取适当措施以尽可能消除或降低由此产生的风险。

17.2. 当患者的安全性取决于内部电源时， 此类器械应配备可确定电源状态的手段， 并且当电源容量处于临界值时， 必要时应在电源容量变为临界值之前， 提供适当警告或指示。

17.3. 器械的设计和制造应尽可能降低产生电磁干扰的风险， 以免影响出现问题的器械或该使用环境下其他器械或设备的操作。

17.4. 器械的设计和制造应具有使器械能够按预期运行的抗电磁干扰能力。

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(1) 1979 年 12 月 20 日关于成员国有关计量单位法律的理事会第 80/181/EEC 号指令，以及废除第 71/354/EEC 号指令（ OJ L39,15.2， p.40）

17.5. 器械的设计和制造应尽可能避免使用者或他人在正常使用过程中或者单一故障条件下意外触电的风险，前提是器械根据制造商的指示正确进行安装和维护。

18. 机械和热风险防护

18.1. 器械的设计和制造应保护使用者和他人免受机械风险。

18.2. 器械应在可预见操作条件下足够稳定。器械应能适当承受可预见工作环境中的压力，并且在其预期寿命期间保持该承受力，符合制造商指示的任何检验和维护要求。

18.3. 当存在由于活动部件、分离或脱离、或物质泄漏造成的风险，则应有相应防护手段。

为器械提供保护的任何防护装置或其他工具，尤其是用于活动部件的装置或工具，应当稳固安全，并且不得干涉其正常操作、或者限制制造商预期的日常维护。

18.4. 应采用适当方式设计和制造器械，确保尽量降低因器械振动引起的风险水平，并考虑利用先进技术和手段限制振动（尤其振动源处），除非振动是特定性能中一部分。

18.5. 应采用适当方式设计和制造器械，确保尽量降低因噪音释放而产生的风险水平，并考虑利用先进技术和手段减少噪音（尤其噪音源处），除非这种噪音是规定性能中组成部分。

18.6. 使用者或他人必须操作连接到电力、气体、液压或气动能量供给源的端口和连接器，应采用适当方式设计和构造此类端口和连接器，确保尽量降低任何潜在风险。

18.7. 当安装或重装某些部件时，可能出现的失误将有可能成为风险的源头，此类部件的设计和构造应完全避免该风险，若无法实现，则应通过在部件和/或其外壳的说明信息完全避免。

当需要知道移动方向以避免风险，相同信息应在活动部件和/或其外壳说明。

18.8. 在正常使用条件下，器械内可接触部件（不包括拟供热或达到给定温度的部件或区域）及其周围环境在正常使用条件下不得达到潜在的危险温度。

19. 针对用于自检或床旁检测的器械造成的风险防护

19.1. 用于自我检测或床旁检测的器械，其设计和制造应考虑到预期使用者的技能和可用手段，以及由于变化而产生的影响，从而使其适用于预期目的。制造商提供的信息和说明应便于预期使用者理解和应用，以使其正确理解器械提供的结果，并避免误导性信息。当在床旁检测的情况下，制造商提供的信息和说明应清楚说明要求使用者的训练水平、资格和/或经验。

19.2. 用于自检或床旁检测的器械其设计和制造应

(a) 如有必要，确保预期使用者在适当训练和/或信息获得后可安全准确地使用器械；

(b) 尽可能降低预期使用者在使用器械和样本以及结果解释时错误的风险。

19.3. 用于自我检测或床旁检测的器械，在可行的情况下，应包含一项程序以使预期使用者可：

(a) 在使用时，验证器械将按照制造商的说明执行；

(b) 若器械未能提供有效的结果，则发出警告。

第 III 章

有关器械随附信息的要求

20. 标签和使用说明书

20.1 制造商需提供的信息的一般要求

各器械应附有识别器械及其制造商的信息，以及所有与使用者或任何其他人员相关的安全与性能信息。此类信息可体现在器械本身、包装或使用说明书中，若制造商有网站，则应在网站上提供并保持更新最新信息，同时考虑到以下因素：

(a) 标签和使用说明的介质、格式、内容、可读性和位置应适合于特定器械、其预期目的和对预期使用者的技术知识、经验、教育或培训。尤其是使用说明书应以预期使用者容易理解的语言撰写，并且在必要时补充图纸和图表。

(b) 标签上所需的信息应在器械本身上提供。若不行，部分或所有信息可能出现在各单元的包装上。若无法单独标记各单元，则应在多个器械的包装上列出信息。

(c) 标签应以人们可读的格式提供，并且可通过机器可读信息（例如射频识别（RFID）或条形码）来补充。

(d) 使用说明应与器械一并提供。但在正当理由和特殊情况下，若器械可在无使用说明书的情况下安全并可按制造商目的使用，则可无需使用说明或可简缩使用说明。

(e) 若有多个器械（除了用于自测或床旁检测的器械之外）供应给单个使用者和/或地点，且购买者同意（其在任何情况下可要求提供免费的进一步的副本），可提供使用说明的单个副本。

(f) 当器械仅限专业使用时，可以非纸张格式（例如电子形式）向使用者提供使用说明，除该器械用于床旁检测时。

(g) 需要传达给使用者和/或其他人的残留风险应作为制造商提供的信息中的限制、预防措施或警戒。

(h) 在适当情况下，制造商提供的信息应采用国际公认的符号形式，同时考虑到预期使用者。使用的任何符号或识别颜色应符合协调标准或CS。若没有特定标准或CS，符号和颜色应说明在随同器械提供的相关文件中。

(i) 在装有可能被视为危险物质或混合物的器械中，考虑到其成分的性质和数量以及其存在的形式，相关危险图形符号和欧洲委员会第1272/2008号法规的标签要求应适用。若无足够的空间将所有信息放在器械本身或其标签上，则相关的危险图形符号应放于标签上，且该法规要求的其他信息应在使用说明中提供。

(j) 除非使用说明书中已提供了所有相关信息，否则应适用欧洲委员会第 1907/2006 号法规规定的安全数据表。

20.2. 标签信息

标签应注明以下全部事项：

(a) 器械的名称或商品名称。

(b) 使用者识别器械以及包含器械预期目的所必需的信息 （在对使用者非清晰可见的情况下）；

(c) 制造商的名称、 注册名称或注册商标及其注册营业地点的地址； 以及授权代表的注册营业地点地址

(d) 授权代表的姓名和地址（若制造商注册营业地点在欧盟以外） ；

(e) 注明该器械是体外诊断医疗器械，或者若器械是“ 性能研究用器械 ” ，则应相应注明；

(f) 注明仪器的批次代码 /批号或序列号， 前面带有词语 LOT 或 SERIAL NUMBER 器械的序列号或等效符号（如适用） 。

(g) 注明根据第 24 条和附录 VI 中 C 部分所述的 UDI 载体；

(h) 注明何时可安全使用器械而不降低使用性能的使用期限， 至少应以年、 月和日（若有关的话）的顺序表示；

(i) 若没有注明可安全使用的日期， 则注明制造日期。 制造日期可作为批次或序列号的一部分，日期应清晰可辨。

(j) 在相关情况下， 注明以重量或体积、 数量计数或这些的任何组合表示的内容净含量或准确反映包装内容的其他术语；

(k) 注明适用的任何特殊储存和 /或处理条件。

(l) 适当时， 注明器械的无菌状态和灭菌方法， 或注明任何特殊微生物状态或清洁状态的声明；

(m) 需要采取的警戒或预防措施， 需要引起器械使用者或其他人的注意。 该信息可保持最小量，在这种情况下，使用说明书中将说明更详细的信息，同时考虑到预期使用者；

(n) 若使用说明书按照第 20 节（f）点的说明没有按纸张形式提供，则所述其可访问性（或可用性）以及可查阅的网站地址（在可能的情况下） ；

(o) 适用时，任何特定的操作说明；

(p) 若器械是一次性使用， 则相应注明。 制造商的一次性使用指示应在整个欧盟内保持一致；

(q) 若器械用于自检或床旁检测，则相应注明

(r) 在快速测定不用于自检或床旁检测的情况下，其明确排除；

(s) 当器械试剂盒包括作为单独器械提供的试剂和制品时， 该器械中的每一个应符合本节中所包含的标签要求和本法规的要求；

(t) 器械和单独组件应在批次适用的情况下进行标识，以允许所有适当的操作来检测器械和可拆卸组件带来的任何潜在风险。在可行和适当的情况下，信息应在器械本身和/或在销售包装上列出（在适当情况下）。

(u) 自检器械的标签应包括以下内容：

(i) 进行测试所需的样本类型（例如血液、尿液或唾液）；

(ii) 对保证测试正常进行的其他材料的需求；

(iii) 获得进一步的建议和帮助的联系方式。

自检器械的名称不得反映制造商规定以外的预期用途。

20.3. 无菌包装：

保持器械无菌条件的包装（无菌包装）上的信息：

(a) 注明无菌包装标识；

(b) 声明该器械处于无菌状态；

(c) 灭菌方法；

(d) 制造商名称和地址；

(e) 器械说明；

(f) 制造月份和年份；

(g) 明确注明使用器械的安全有效日期；，并至少按年份和月份表示，并在相关时附上该订单的日期；

(h) 检查使用说明书中的说明，若无菌包装损坏或在使用前不小心打开，该如何处理。

20.4. 使用说明书中的信息

20.4.1 使用说明书应包含以下全部信息：

(a) 器械的名称或商品名称；

(b) 使用者唯一识别器械的严格必要的信息；

(c) 器械的预期用途：

(i) 需检测和/或测量什么；

(ii) 其功能（例如，筛选、监测、诊断或辅助诊断、预后、预测、伴随诊断）；

(iii) 要在下列情况下提供的具体信息：

-生理或病理状态；

-先天性身体或精神损伤；

-医学病症或疾病的倾向；

-确定与潜在接受者的安全性和兼容性；

-治疗反应的预测；

-治疗措施的定义或监测；

(iv) 是否为自动化；

(v) 是定性、半定量还是定量；

(vi) 所需的样品类型；

(vii) 适合的测试人群。

(viii) 对于伴随诊断，其为伴随测试的相关医药产品的国际非专有名称（INN）。

(d) 指明该器械是体外诊断医疗器械，或者若器械是“性能研究用器械”，则应相应指明；

(e) 适当的预期使用者（例如，自我测试、床旁诊断和实验室专业使用、保健专业人员）；

(f) 测试原理；

(g) 定标液和质控品其使用的任何限制说明（例如，仅适用于专用仪器）；

(h) 试剂及其使用的任何限制（例如，仅适用于专用仪器）和试剂组成成分的性质和试剂或试剂盒的有效成分的量或浓度的说明以及（在适当情况下）该器械包含可能影响测量的其他成分的声明；

(i) 提供的物品的清单和所需但未提供的特殊物品清单；

(j) 对于旨在与其他器械和/或通用设备结合使用或与其安装或连接的器械：

- 以识别此类器械或设备的信息，以便获得经验证和安全的组合，包括关键性能特性和/或
- 有关器械和设备组合的任何已知限制的信息。

(k) 任何适用的特殊储存（例如，温度、光、湿度等）和/或处理条件的指示；

(l) 使用中的稳定性，包括储存条件和在容器第一次打开之后的有效期，以及工作溶液的储存条件和稳定性（在相关情况下）；

(m) 若器械以无菌形式提供，则指明其无菌状态、灭菌方法并进行说明（若无菌包装在使用前损坏）；

(n) 允许通知使用者有关器械的任何警戒、预防措施、采取的措施和使用限制的信息。该信息应酌情包括：

(i) 警戒、预防措施和/或在器械发生故障或其劣化的情况下采取的措施（可通过其可影响性能的外观变化表示）；

(ii) 警戒、预防措施和/或就暴露于合理可预见的外部影响或环境条件采取的措施（例如磁场、外部电和电磁效应、静电放电、与诊断或治疗流程相关的辐射、压力、湿度、或温度）；

(iii) 警戒、预防措施和/或就特定诊断研究、评估、治疗处理或其他流程期间器械的合理可预见的存在所造成的干扰风险采取的措施（例如，器械发出的影响其他设备的电磁干扰）；

(iv) 与引入器械含有或包含 CMR 物质或具有内分泌干扰性质或可能导致患者或使用者的致敏或过敏反应的材料相关的预防措施；

(v) 若器械是一次性使用，则相应指明。制造商的一次性使用说明应在整个欧盟内保持一致；

(vi) 若器械可重复使用，则须包括有关允许重复使用的过程的信息，

包括清洁、 消毒、 净化、 包装和经过验证的再消毒方法 （适当时）。应提供信息以识别该器械何时不得再使用，例如，材料劣化迹象或允许重复使用的最大数量。

(o) 与器械中包含的潜在传染性物质相关的任何警戒和 /或预防措施；

(p) 在相关情况下，对特殊设施（例如洁净室环境）或特殊培训（例如辐射安全）或器械预期使用者的特定资格的要求；

(q) 样品的收集，处理和制备条件；

(r) 对于制造商预期使用的器械，在器械准备使用前（例如灭菌、最终装配、校准等）对器械的任何预备处理或处理的细节；

(s) 验证器械是否正确安装并是否准备好安全运行以及按制造商预期使用（若相关）：

- 预防性和定期维护 （包括清洁和消毒） 的性质和频率的详细信息；
- 任何消耗部件的标识和更换方法；
- 任何必要的校准信息，其用以确保器械在其预期寿命期间正常和安全地运行；
- 减轻安装、校准或维修器械的人员所遇到的风险的方法。

(t) 适用时，质量控制流程的建议；

(u) 校准品和质控材料赋值的计量可追溯性，包括对应用高一级的参考材料和/或参考测量流程的识别，以及关于最大（自允许）批次间变化的信息，以及相关图和测量单位；

(v) 包括计算和结果解释的分析程序，若考虑进行任何证实试验，则相关；适用时，使用说明应附有有关图表和计量单位提供的批次间变化的信息；

(w) 分析性能特征，如分析灵敏度、分析特异性、真实性（偏差） 、精密度（重复性和重现性），精确性（由真实性和精密度导致） 、检测限和测量范围 （控制已知相关干扰、交叉反应和方法的限制的信息） 、测量范围、线性和使用者使用可用的参考测量流程和材料的信息；

(x) 本附录第 9.1 节中定义的临床性能特征；

(y) 计算分析结果的数学方法；

(z) 与阈值、诊断敏感性和诊断特异性、阳性和阴性预测值等相关的临床性能特征；

(aa) 正常和受影响人群有关的参考区间；

(ab) 关于可能影响器械性能的干扰物质或局限性的信息（例如高脂血症或溶血的可视性证据，标本年龄） ；

(ac) 为便于安全处理器械试剂盒和与其一起使用的耗材 （如有），应采取的警戒或预防措施。该信息应包括：

(i) 感染或微生物危害（例如，被人类潜在感染性物质污染的耗材） ；

(ii) 环境危害（例如，可能发射危险级别辐射的电池或材料） ；

(iii) 物理危害（例如，爆炸） 。

(ad) 制造商的名称、注册名称或注册商标及其可联系到的注册营业地址及生产地址，以及售后服务的电话号码和 /或传真号码和 /或网站地址；

(ae) 使用说明书的发行日期，或者若对其进行了修订，最新版使用说明书核准及修改日期与标识符（明确指出所做修订之处） ；

(af) 告知使用者任何涉及器械的严重不良反应事件应向制造商以及使用者和 / 或患者所在成员国的主管机构报告；

(ag) 当器械试剂盒包括作为单独器械使用的试剂和制品时，该器械套件中的每一个试剂应符合本节中所包含的使用说明要求和本法规的要求；

(ah) 用于包含可编程电子系统的器械，包括器械自身的软件或软件、硬件最低要求、网络特性以及对于运行软件所需的安全措施（包括防止未经授权的访问）。

20.4.2.此外，自测器械的使用说明书还应遵循以下全部原则：

(a) 应提供测试程序详情，包括试剂制备、样本采集和 /或如何运行测试并解释结果的准备和信息；

(b) 可省略具体细节，前提是制造商提供的其他信息足以让使用者了解如何使用器械和理解器械所产生的结果；

(c) 器械的预期用途应提供足够的信息，让使用者了解医疗背景，并让预期使用者能够正确地理解结果；

(d) 应以预期使用者易理解的方式表示和呈现结果；

(e) 应向使用者提供关于（若出现阳性结果、阴性结果或不明确的结果） 、测试限制和假阳性或假阴性结果可能性采取的措施建议。还应提供任何可影响测试结果的信息（如年龄、性别、月经、感染、运动、禁食、饮食或药物） ；

(f) 自测类器械所提供的信息应包括一份声明，明确指出在未咨询恰当的健康专业人士时不得做出任何相关的医疗决定， 以及疾病影响与患病率的信息，以及在适用情况下，对于特定欧盟国家该器械上市后使用者可获得进一步的建议（例如全国热线，网站等）的信息；

(g) 对于监测已确诊的疾病或病症的自测器械，该信息应指出，只有患者接受过相关的培训，才可采用这种疗法。

附录 II

技术文件

制造商制定的技术文件及其摘要（如适用）应以清楚，有序地，易于检索和明确的方式提出，并应特别包括本附录中说明的要素

1. 器械说明与性能指标，包括变型和附件

1.1. 器械说明与性能指标

(a) 产品或商品名和器械的一般说明，包括其预期目的和预期使用者；

(b) 在附录 VI 的 C 部分中所述的基本 UDI-DI 器械标识符，只要该器械的标识应基于 UDI 系统，或以其他方式通过产品代码、目录编号或其他可追溯的明确参考号来清楚识别，允许可追溯性；

(c) 器械的预期目的，可能包括以下信息：

(i) 将检测和 /或测量什么；

(ii) 其功能 （例如， 筛选、 监测、 诊断或辅助诊断、 预后、 预测、 伴随诊断）；

(iii) 旨在检测、定义或区分特定的病症或风险因素；

(iv) 是否为自动化；

(v) 是定性、半定量还是定量；

(vi) 所需样本类型；

(vii) 测试适用人群；

(viii) 预期使用者。

(ix) 此外，对于伴随诊断，相关的目标人群和相关的医药产品。

(d) 检测原理的说明或仪器操作原理的说明；

(e) 产品可作为器械使用的限定依据；

(f) 器械的风险等级和按照附录 VIII 应用的分类规则的依据；

(g) 组成成分的说明及反应成分（例如抗体、抗原、核酸）的说明（如适用）；以及下列项目（如适用）：

(h) 样本收集、储存、运输说明或建议使用的规格参数的说明；

(i) 对于自动检测的仪器：相关检测特征或专用检测的说明；

(j) 对于自动检测：相关仪器特征或专用仪器的说明；

(k) 任何与器械一起使用的软件的说明；

(l) 市场上可用器械的各种配置 /变量的说明或完整列表；

(m) 器械附件、其他器械、以及其他旨在与该器械结合使用的非器械产品的说明。

1.2. 对前一代和类似器械的引用

(a) 对制造商生产的前一代器械的概述，如有；

(b) 在欧盟（ EU）或国际市场上发现可用的类似器械的概述，如有。

2. 制造商应提供的信息

一整套

(a) 器械及其包装， 例如在特定管理条件下的单机包装、 销售包装、 运输包装上的标签（使用器械预期销售成员国可接受的语言）

(b) 使用说明书（使用器械预期销售所在成员国可接受的语言） ；

3. 设计与制造信息

3.1 设计信息

标明器械设计阶段的信息。其中应包括：

(a) 器械含有的或推荐使用的关键成分（如抗体、抗原、酶、核酸引物）的说明；

(b) 对于仪器，主要子系统、分析技术（例如工作原理、控制机制） 、专用计算机硬件和软件的说明；

(c) 对于仪器和软件，整个系统的概述；

(d) 对于软件，结果解释方法学的说明（即算法） ；

(e) 对于自测器械或床旁检测的器械， 让其适用于自测或床旁检测的设计方面的说明。

3.2 生产信息

（a）了解制造流程的信息，如成品器械的生产、组装、最终产品测试和包装。质量管理体系或其他适用的符合性评估流程的审核时，应提供更详细的信息；

（b）确定进行生产制造的所有场址，包括供应商和分包商。

4. 通用安全与性能要求

文件应包含其符合附录 I 所规定的适用于器械通用安全与性能要求的证明， 并考虑到其预期用途，包括为满足这些要求而采用的理由，验证和确认。该证明应包括：

(a) 适用于器械的通用安全与性能要求和其他不适用的理由；

(b) 证明其符合通用安全与性能要求的方法；

(c) 协调标准或应用的 CS 或采用的其他解决方案；

(d) 提供证据证明符合各协调标准， CS 或用于证明符合通用安全与性能要求的文件，此信息应在完整的技术文档中包含对此类证据的位置的交叉引用， 若适用，

还应包括技术文档总结。

5. 风险 /利益分析和风险管理

文件应包含

(a) 在附录 I 的第 1 和和 8 章节中所述的风险 /利益分析；

(b) 在附录 I 的第 3 章节中所述的风险管理采取的方案和结果。

6. 产品验证与确认

文件应包含所进行的所有验证与确认测试和 /或研究的结果和关键分析，以证明器械符合本法规的要求，特别是证明其符合适用通用安全与性能要求。

这包括：

6.1. 器械分析性能信息

6.1.1. 样品类型

本章节将说明可使用的不同样本类型，包括其稳定性（例如储存条件、适用的运输条件、样本提取与分析之间的不同时段信息（鉴于时间关键分析方法）和储存条件（例如持续时间、温度控制和冷冻 /解冻循环）。

6.1.2. 分析性能特征

6.1.2.1. 测量准确性

(a) 测量真实性

本章节应提供测量程序的真实性信息，并详细汇总数据，以评估所选方法是否恰当以及证明真实性。只在认证参考材料或认证方法可用时，真实性测量才适用于定量与定性化验。

(b) 测量精密度

本章节应说明重复性与再现性研究。

6.1.2.2. 分析灵敏度

本章节应包括有关研究设计和结果的信息。应说明样本的类型与制备，包括基质、分析物水平以及如何建立水平。还应提供以每种浓度测试的重复次数，以及用于测定灵敏度的计算方法 。

6.1.2.3. 分析特异性

本章节说明干扰和交叉反应研究，以确定样本中其他物质 /试剂存在时的分析特异性。

应提供检测中可能出现干扰和交叉反应的物质 /试剂的评价，所测试的物质 /试剂类型和浓度，样本类型，分析物测试浓度和结果的信息 。

干扰物和交叉反应物质 /试剂（很大程度上取决于测试类型和设计）可能来自外源或内源，如：

(a) 用于患者治疗（例如医药产品）的物质；

(b) 患者摄取的物质（例如酒、食物） ；

(c) 样本制备期间添加的物质（例如防腐剂、稳定剂） ；

(d) 在特定样本类型中常见的物质（例如血红蛋白、脂质、胆红素、蛋白质） ；

(e) 类似结构的分析物（例如前体、代谢物）或与测试条件无关的医疗条件，包括检测结果为阴性，但在可模仿测试的条件下为阳性的样本。

6.1.2.4. 定标液和质控品值的计量学溯源性

6.1.2.5. 检测的测量范围

本章节应包含测量范围的信息（无论测量系统为线性与非线性测量系统），包括检测限制，也应阐述如何建立这些范围。

这些信息应包括样本类型、样本数量、重复次数和制备的说明，包括基质、分析物水平和如何建立水平。如适用，应增加高剂量钩状效应的说明和支持缓解（例如稀释）步骤的数据。

6.1.2.6. 检测临界值的定义

本章节应提供分析数据的结论及研究设计的说明，包括确定检测临界值的方法，比如：所研究的人群：人口统计、选择、包含和排除的标准

(a) 个体数；

(b) 方法或样本特性；

(c) 统计方法，如受试者工作特征（ ROC）生成结果，并定义灰色地带 /可疑地带（如适用）。

6.1.3. 根据附录 XIII，分析性能报告。

6.2. 关于临床性能和临床证据的信息。性能评估报告

按照附录 XIII，文件应包含性能评估报告。包括科学有效性、分析与临床性能的报告，以及这些报告的综合评估。

技术要求资料，应包括和 /或完全参考附录 XIII 第 2 章节所述的临床性能研究文件。

6.3. 稳定性（不包括样本稳定性）

本章节说明器械有效期、使用期间稳定性和运输稳定性研究。

6.3.1. 声称的有效期

本章节应提供关于稳定性测试研究的信息，以支持声明的有效期。 测试应在至少三个不同批次上进行，这些批次基本上等同于常规生产条件下制造的（这三个批次不需要是连续批次）。从加速研究或对实时数据的推断得出的数据对于初始声称的有效期是可接受的， 但随后应进行实时稳定性研究。

此类详细的信息应包括：

(a) 研究报告（包括方案、批号、验收标准和测试间隔）；

(b) 当加速研究用于进行对实时研究的预估时，加速研究所使用的方法；

(c) 结论和声称的有效期。

6.3.2. 使用期间的稳定性

本章节应提供关于器械 （无论实际或模拟）实际日常使用的 一批次使用期间稳定

性的研究信息。对于自动化仪器，这可能包括开封的瓶稳定性和 /或机载稳定性。

在自动化仪器的情况下，若声称校准稳定性，则应包括支持数据。

此类详细的信息应说明：

(a) 研究报告（包括方案、验收标准和测试间隔） ；

(b) 结论和声称的使用期间稳定性。

6.3.3. 运输稳定性

本章节应提供关于一批器械的运输稳定性研究的信息，以评估器械对预期运输条件的 适应性。

在真实和 /或模拟的条件下， 可进行运输研究； 运输研究也应包括可变的运输条件，如极热和 /或极冷。

此类信息应说明：

(a) 研究报告（包括方案、验收标准） ；

(b) 模拟条件所用的方法；

(c) 结论和建议的运输条件。

6.4. 软件的验证与确认

文档应包含在成品器械中使用的软件确认的依据。此信息通常应包括内部执行的所有验证、确认和测试的结果，并在最终发布之前在实际使用者环境中适用。它还应解决标签中标识的所有不同的硬件配置以及操作系统（如适用） 。

6.5. 在特定情况下所需的其他信息

(a) 对于在无菌或限定的微生物条件下投放于市场的器械，相关生产步骤的环境条件的说明。 在市场上以无菌条件放置的装置的情况下，说明所使用的方法，包括关于包装，灭菌和无菌维持的确认报告。确认报告应涉及生物负载测试，热原测试 和消毒剂残留物测试（如适用） 。

(b) 对于包含动物、人或微生物来源的组织、细胞和物质的器械，有关这种材料来源和采集条件的信息。

(c) 对于投放于市场的具有测定功能的器械，为确保规范中给定的准确性而采用的方法说明。

(d) 若为完成预期操作而将器械连接到其他设备上，应提供这种组合的说明，该说明应根据制造商规定的特征，包括连接到任意此类器械时其符合通用安全与附录 I 中规定的性能要求的证据。

附录 III

关于上市后监管的技术文件

由制造商草拟的关于上市后监管的技术文件应按照第 78 条至第 81 条条款的说明，以清楚的、有序的、易搜索的和明确的方式呈现，特别应该包括本附录中说明的要素：

1. 符合第 79 条说明的上市后监管计划。

在上市后监管计划中，制造商应证明其履行了第 78 条中所述的义务。

(a) 上市后监管计划应所述可用信息的收集与利用，尤其是：

- 有关严重事件的信息，包 PSURS 的信息和现场安全纠正措施,
- 有关非严重事件的记录和有关任何不良副作用的数据,
- 趋势报告的信息,
- 相关专家或技术文献、数据库和 /或登记表,
- 包括使用者、经销商和进口商提供的反馈和投诉信息，及
- 关于类似医疗器械的可获得的公开信息。

(b) 上市后监管计划至少应包括：

- 收集（ a）中所述的所有信息的前瞻性与系统化流程。该流程应正确地说明器械的性能，也将该器械与投放于市场的类似产品进行比较；
- 有效且适当的方法与流程，用于评估所收集的数据；
- 合适的指标和阈值，用于风险收益分析和风险管理连续的重新评估，如附录 I 第 3 节所所述的；
- 有效且适当的方法和工具，用于调查现场收集的投诉并分析相关市场经验；
- 根据第 83 条创建的用于管理适用于趋势报告的事件的方法和方案，包括用于建立在事件发生频率或严重程度上以及观察期的统计学显著增加的方法和方案；
- 用于与主管机构、认证机构、经济运营商和使用者有效沟通的方法和方案；
- 用于履行第 78、 79 及 81 条规定的制造商的义务的流程的参考；
- 用于确定并采取适当的措施，包括纠正措施的系统化流程；
- 用于跟踪并确定哪些器械需要纠正措施的有效工具；
- 根据附录 XIII 的 B 部分的上市后性能跟踪计划， 或上市后性能跟踪不适用的理由。

2 在第 81 条中所述的定期安全更新报告和在 80 条中所述的上市后监管报告。

附录 **IV**

欧盟符合性声明

欧盟符合性声明应包括以下信息：

1. 如已注册， 在第 28 条中所述的制造商名称、 注册商品名或注册商标及其授权代表 （如适用）、可联系到的注册营业地点以及建立的工厂地点；

2. 由制造商自行负责发出的符合标准声明；

3. 第-附录 VI 的 C 部分所所述的 UDI-DI ；

4. 欧盟符合性声明应包含包括产品和商标名称、产品代码、货号或其他可标示或追溯的器械产品识别信息如照片（如适用） ）以及预期用途。除了产品或商品名称，可标识和追溯的信息可通过第 3 条中所述的基本 UDI-DI 来提供；

5. 器械的风险等级应符合附录 VIII 中的规定；

6. 本条例适用的器械的符合性声明应符合本法规和其他（规定发布符合性声明）的欧盟立法（如适用） ；

7. 关于符合性声明所用的 CS 的任何参考文献；

8. 如适用，公告机构的名称和标识号，所执行的符合性评估流程的说明和所签发的证书的标识；

9. 如适用，额外的信息；

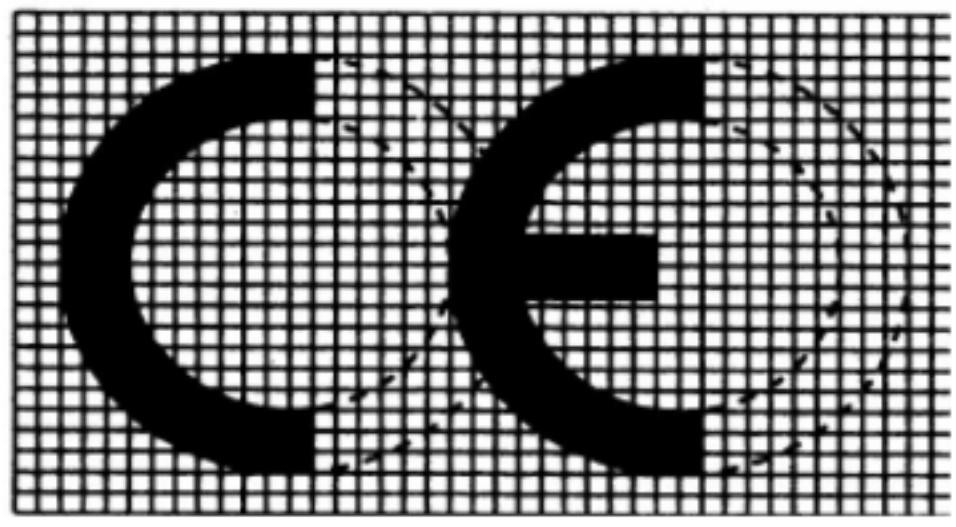
10. 签发声明地点和日期、签字人的姓名和职务、以及代签人的签名。

_____

附录 V

CE 符合性标志

1. “ CE ”标识必须包含前缀“ CE ”，并采用下面形式：



2. 若缩小或放大 CE 标识，应遵守上述渐变图的比例。

3. 在垂直方向上， CE 标识的各个部分应具有基本相同的尺寸，不小于 5 mm。此最小尺寸不针对小型器械。

附录 VI

根据第 26（3）和 28 条提交的注册器械和经济运营商资料，根据第 25 和 26 条提供给 UDI 数据库的核心数据元素与 UDI-DI，和 UDI 系统

第 A 部分

根据第 26(3)和 28 条提交的注册器械和经济运营商信息

制造商、授权代表（如适用）、进口商（如适用）应提交第 1 节中所述的信息，还应确保第 2 节中所述的有关其器械的信息是完整和正确的，并由相关方更新。

1. 与经济运营商有关的信息

1.1. 经济运营商的类型（制造商、授权代表或进口商）；

1.2. 经济运营商的名称、地址和联系方式；

1.3. 若信息由 1.1 中的其他角色代为提交，还应提供提交人的姓名、地址和联系方式；

1.4. 第 15 条中所述的法规符合性负责人的姓名、地址和联系方式；

2. 与器械有关的信息

2.1. 基本 UDI-DI，

2.2. 公告机构签发的证书的类型、编号、到期日和签发该证书的公告机构的名称或标识号及在证书上显示的并由公告机构输入电子系统中的公告机构及证书信息的链接）；

2.3. 器械应投放或已经投放的欧盟成员国；

2.4. 若器械归为 B、C 或 D 类：器械已经或应该投放的成员国；

2.5. 存在人类来源的组织、细胞或衍生物（是/否）；

2.6. 存在动物来源的组织、细胞或在欧盟第 722/2012 号法规中所述的其衍生物（是/否）；

2.7. 存在微生物来源的细胞或物质（是/否）；

2.8. 确定器械的风险等级；

2.9. 性能研究的单一标识号（如有），

2.10. 若器械由第 10(14)条中所述的另一个法人或自然人设计和制造，需提供该法人或自然人的名称、地址和联系方式；

2.11. 若器械归为 C 类或 D 类，需提供安全性和性能的总结；

2.12. 器械的状态（上市、退市、召回、现场安全纠正措施启用）；

2.13. 判断器械是否为 新 器械。

新 器械应满足：

(a) 近三年欧盟市场中不存在连续销售的，具有类似分析物或其他参数的此等器械；

(b) 近三年欧盟市场中不存在利用类似技术程序分析特定分析物或其他参数有关的器械。

2.14. 无论器械是否旨在自测或床旁检测应说明。

第 **B** 部分

根据第 **25** 和 **26** 条提供给 **UDI** 数据库的核心数据元素与 **UDI-DI**

制造商应向 UDI 数据库提供 UDI-DI 和以下与制造商和器械相关的信息：

1. 各程序包配置的数量,

2. 如适用，按照第 24(6)条，基本的 UDI-DI 和任何额外的 UDI-DIS ；

3. 如何控制器械生产的方式（限制使用日期或生产日期、批号、序列号） ；

4. 如适用， 使用单位 的 UDI-DI （未给 使用单位 的器械分配 UDI 时，应分配 使用单位 的 UDI-DI ，以将器械的使用与患者关联起来） ；

5. 如标签所示的制造商的名称和地址,

6. 按照第 28(2)条发布的 SRN,7. 如适用，授权代表的名称和地址（如标签所示）

8. 按照第 23 条，医疗器械命名法规。

9. 器械的风险等级；

10. 如适用，商品名 /商标名；

11. 如适用，器械的型号、参考号或货号；

12. 额外的产品说明（可选） ；

13. 如适用，存储和 /或处理条件（如标签或使用说明所示） ；

14. 如适用，器械的额外商品名；

15. 标记为一次性使用器械（是 /否）；

16. 如适用，最大重复使用次数；

17. 无菌标签的器械（是 /否）；

18. 使用前需消毒（是 /否）；

19. 额外信息的 URL ，如电子使用说明（可选） ；

20. 如适用，重要警告或禁忌征候；

21. 器械状态（市场上、退市、召回、现场安全措施启用） 。

第 **C** 部分

UDI 系统

1. 定义

自动标识和数据捕获（下文为 AIDC ）

AIDC 是一种自动捕获数据的技术。 AIDC 技术包括条形码、智能卡、生物识别和 RFID 。

基本的 UDI-DI

基本的 UDI-DI 是器械模型的主要标识符， 是在器械使用单位的层面上分配的器械标识。其也是在 UDI 数据库中记录的关键，也应在相关的证书和欧盟符合性声明中被引用。

使用单位 DI

在器械使用单位（例如，在数个包装在一起的多个单位相同器械）的单个器械层面上未标记 UDI 的情况下，使用单位 DI 用以将器械的使用与患者及其相关的数据关联起来。

可配置器械

可配置器械是一种由数个组件组成的器械。在多种配置中，这些组件可能由制造商组装。那些独立的组件可能本身就是器械。

配置

配置是设备项的组合，由制造商指定。这些设备项一起运作，以达成器械预期用途或目的。可修改、调整或定制设备项的组合，以满足客户特殊需求。

UDI-DIU

DI-DI 是专用于器械模型的唯一数字或字母数字码，也被用作 UDI 数据库中所保存的信息的“ 存取键 ” 。

人类可读标识（ HRI ）

HRI 是 UDI 载体中编码的数据字符的易读标识。

包装等级

包装等级意为器械包装的各种等级，包含固定数量的器械，如各个纸箱或箱子。

生产标识符（ UDI-PI ）

UDI-PI 是一种数字或字母数字码，用于识别器械生产单位。

不同类型的 UDI-PI 包括序列号、批号、软件标识和制造或到期日或两种类型日期。

无线射频标识（ RFID ）

RFID 是一种以标识为目的通过无线电波交换阅读器和电子追踪器之间的数据来进行通信的技术。

运输容器

运输容器是一种相关利用物流系统专用流程控制溯源的集装箱。

唯一器械标识（以下简称“ UDI ”）

UDI 是一系列数字或字母数字字符，通过全球接受的器械标识和编码标准来创建。在市场上，允许明确标识特定器械。 UDI 由 UDI-DI 和 UDI-PI 组成。

UDI 载体

“ 唯一 ”这个词并不意味着各生产单位的序列变化。

UDI 载体是通过使用 AIDC 及其 HRI （如适用）传达 UDI 的工具。

除了别的以外，载体还包括 ID / 线性条形码、 2D / 矩阵条形码、 RFID 。

2. 一般要求

2.1. UDI 的附注是一个额外的要求 - 不替换本法规附录 I 规定的任何其他标记或标签要求。

2.2. 制造商应指定并维护其器械的唯一 UDI 。

2.3. 只有制造商可在其器械或包装上设置 UDI 。

2.4. 只能使用由欧盟委员会根据第 24（2）条所指定实体提供的编码标准。

3. **UDI** （唯一器械标识）

3.1. UDI 应位于器械本身或其包装上。更高级别的包装应有其自己的 UDI 。

3.2. 运输容器应豁免第 3.1 节规定的要求。 例如， 物流设备上无需有 UDI ；当医疗服务机构订购多台使用 UDI 或单个器械型号的器械，而且制造商将这些器械放置在一个容器内运输或用以保护单独包装的器械时，不要求运输容器（物流设备）上有 UDI 。

3.3. UDI 应包含两部分：一个 UDI - DI 和一个 UDI - PI 。

3.4. UDI - DI 在每一级别的器械包装上都是唯一的。

3.5. 若标签上有批号、序列号、软件标识或有效期限，则这些信息应是 UDI - PI 的一部分。若标签上同时还标有生产日期，则 UDI - PI 中无需包含生产日期。若在标签上只有生产日期，则应将其用作 UDI - PI 。

3.6. 被视为器械且可在市场上购买的各组件应有其单独 UDI , 除非此类组件是以单独 UDI 销售的可配置器械的一部分。

3.7. 套件应有其自己的 UDI 。

3.8. 制造商应根据相关编码标准为器械指定 UDI 。

3.9. 在有可能导致器械的错误识别和 /或其追溯性不明确时， 尤其是以下任何 UDI 数据库元素发生的变化需要新的 UDI - DI 时，将需要提供新的 UDI - DI 。

(a) 品牌名称或商标,

(b) 器械类型或型号,

(c) 标记为一次性使用,

(d) 无菌包装,

(e) 使用前需消毒,

(f) 包装中所提供器械的数量,

(g) 严重警告或禁忌症。

3.10. 使用自有标签对器械进行重新包装或重新标记的制造商应保留原始器械制造商（OEM）的 UDI 记录。

4. UDI 载体

4.1. UDI 载体（UID 的 AIDC 和 HRI 表示）应放置在标签和所有更高级别的器械包装上。更高级别的包装不包括运输容器。

4.2. 若使用包装的器械上有明显的空间限制, UDI 载体可放置在下一个更高级别的包装上。

4.3. 对于单独包装和添加标签的 A 类和 B 类一次性使用器械, UDI 载体无需出现在包装上，但其应出现在更高级别的包装上，例如，包含数个包装的纸箱。但当预期医疗服务机构不能获得如家庭医疗保健设置更高级别的器械包装时, UDI 应放置在包装上。

4.4. 对于专门用于零售销售点（ POS）的器械, AIDC 中的 UDI-PIS 无需显示在销售点包装上。

4.5. 当除 UDI 载体外的 AIDC 载体是产品标签的一部分时, UDI 载体应易于识别。

4.6. 若使用线性条形码，则 UDI - DI 和 UDI - PI 可在两个或更多的条形码中进行级联或非级联。线性条形码的所有部分和元素应是可区分和可识别的。

4.7. 若存在限制在标签上使用 AIDC 和 HRI 的显著约束，则标签上只需要出现 AIDC 格式。对于预期在医疗服务机构以外使用的器械（例如家庭护理器械） ，应在标签上使用 HRI 格式，即使这意味着并无空间留给 AIDC 。

4.8. HRI 格式应遵循 UDI 代码颁发实体的规则。

4.9. 若制造商使用 RFID 技术，则应在标签上提供符合颁发实体所规定标准的线性或二维条形码。

4.10. 可重复使用的器械上应带有 UDI 载体。若可重复使用的器械在患者使用之间需要消毒、杀菌或重新处理，则此类器械的 UDI 载体应为永久性，而且在每次处理后仍可读，以便于在整个预期使用寿命内对器械的再次使用。

4.11. UDI 载体在器械正常使用和预期使用寿命期限内应可读。

4.12. 若 UDI 载体易于通过器械的包装读取或扫描，则 UDI 载体无需出现在包装上。

4.13. 由多个部件组成且在首次使用前必须完成装配的单独成品器械可只在一个部件上带有 UDI 载体。

4.14. UDI 载体的位置应合理，以使在正常操作或储存期间可进行 AIDC 。

4.15. 包括“ UDI - DI ”的条形码载体还可包含器械操作的基本数据或其他数据。

5. UDI 数据库的一般原则

5.1. UDI 数据库应支持本附录第 B 部分中所述的所有 UDI 数据库核心数据元素的使用。

5.2. 制造商应负责 UDI 数据库中识别信息和其他器械数据元素的首次提交和更新。

5.3. 应运用正确的方法和流程对提供的数据进行确认。

5.4. 制造商应定期验证其投放到市场上的器械相关的所有数据的准确性，除非这些器械从市场上撤出。

5.5. UDI 数据库中存在器械 UDI - DI 并不意味着该器械符合本法规的规定。

5.6. 数据库应允许器械不同包装级别的链接。

5.7. 当将器械投放到市场时，应提供新的 UDI - DIS 数据。

5.8. 当对不需要新 UDI - DI 的元素进行更改时，制造商应在 30 天内更新相关的 UDI 数据库记录。

5.9. 在可能的情况下， UDI 数据库应使用国际公认的数据提交和更新标准。

5.10. UDI 数据库的使用者界面应包括所有欧盟官方语言。但为减少翻译，应尽可能减少自由文本字段的使用。

5.11 退出市场器械的相关数据应保存在 UDI 数据库中。

6. 特定器械类型的规则

6.1. 可重复使用的器械，是套件的一部分，而且在使用期间需要对其进行清洁、消毒、灭菌或重新处理。

6.1.1. 此类器械的 UDI 应置于器械上，而且在各操作程序后都是可读的，以便于器械的下次使用；

6.1.2. 制造商应对 UDI-PI 的特性（例如批号或序列号）进行定义。

6.2. 器械软件

6.2.1. UDI 指定标准

应按软件的系统级别指定 UDI 。只有可单独销售的软件和本身构成医疗器械的软件才应遵循该要求。

软件标识应视为制造控制机制，并显示在 UDI - PI 中。

6.2.2. 当存在改变以下方面的变化时，需要新的 UDI - DI ：

(a) 原始性能，

(b) 软件安全性或预期用途。

(c) 数据解释。

这些变化可能包括新的或修改的算法、数据库结构、操作平台、架构、新的使用者界面或用于互操作性的新渠道。

6.2.3. 次要软件版本修订只需要一个新的 UDI - PI （而非新的 UDI - DI ）：

次要软件版本修订应通过新的 UDI - PI 予以识别；

次要软件版本修订通常与错误修复、可用性增强（不是出于安全目的） 、安全补丁或运行效率相关。

次要软件版本修订应通过制造商的特定标识予以识别。

6.2.4. 软件的 UDI 配置标准

(a) 当软件通过物理介质 （如 CD 或 DVD ）进行交付时，各包装级别应带有人类可读和完整 UDI 的 AIDC 表示。应用于包含软件及其包装的物理介质的 UDI 必须与分配给系统级软件的 UDI 相同。

(b) UDI 应以容易读取的纯文本格式（例如, “ 关于 ”文件或包括在启动屏幕上）提供在使用者容易查看的屏幕上。

(c) 缺少使用者界面的软件（例如，用于图像转换的中间软件）应能够通过应用程序编程接口（ API）发送 UDI ；

(d) 软件的电子显示器上只需要 UDI 的人类可读部分。 电子显示器上不需要使用 AIDC 的 UDI 标记，例如, “ 关于 ”菜单、启动画面等。

(e) 软件 UDI 的人类可读格式应包括颁发实体的所使用标准的应用标识符 （AI ），以帮助使用者识别 UDI 并确定用来创建 UDI 的标准。

附录 **VII**

公告机构需满足的要求

1. 组织和一般要求

1.1. 法人资格和组织结构

1.1.1. 应根据成员国的国内法，或根据与欧盟达成该方面协议的第三国的法律来建立一个公告机构，并应对其法人资格和地位进行全面记录。该记录应包括关于所有权和对公告机构行使控制权的法人或自然人的信息。

1.1.2. 若公告机构是作为较大组织一部分的法人实体，则该组织的活动及其组织结构和管理以及与公告机构的关系应清楚地记录在案。在这种情况下，第 1.2 节的要求适用于公告机构和其所属的组织。

1.1.3. 若公告机构全部或部分拥有在成员国或第三国建立的法人实体，或自身由另一法人实体所拥有，则应对这些实体的活动和责任，以及其与公告机构的法律和业务关系进行明确的定义和记录。根据本法规进行符合性评估活动的这些实体所属人员应遵守本法规的适用要求。

1.1.4. 公告机构的组织结构、责任分配、汇报程序和运作应能确保其对所进行符合性评估活动的履行和结果置信。

1.1.5. 公告机构应清楚地记录其组织结构、高层管理人员和其他可能影响符合性评估活动履行和结果的人员的职能、职责和权限。

1.1.6. 公告机构应明确对以下各项具有最高决策权和责任的高层管理人员：

(a) 为符合性评估活动提供足够的资源；

(b) 制定公告机构运作流程和政策；

(c) 公告机构监管流程、政策和质量管理体系的实施；

(d) 监管公告机构的财务；

(e) 公告机构的活动和决定，包括合同协议；

(f) 在必要时向人员和（或）委员会授予执行既定活动的权力；

(g) 与负责公告机构的主管机构的互动，以及与其他主管机构、委员会和其他公告机构沟通的义务。

1.2. 独立性和公正性

1.2.1. 公告机构应是独立于进行符合性评估活动的产品制造商的第三方机构。公告机构也应独立于与产品利益相关以及对制造商有竞争关系的任何其他经济运营商。这并不妨碍对竞争制造商的符合性评估活动。

1.2.2. 公告机构的组织和运作应保障其活动的独立性、客观性和公正性。公告机构应记录和实施一种结构和流程，以保障其公正性，并在其整个组织、人员和评估活动中促进和使用公正性原则。 这些流程应确保对任何可能出现利益冲突情况的识别、调查和解决，包括在到公告机构就职之前参与器械领域的咨询服务（的人员） 。调查、结果及其解决方案应记录在案。

1.2.3 公告机构、其高层管理人员及负责执行符合性评估任务的人员不得

(a) 是所评估器械的设计师、制造商、供应商、安装者、购买者、所有者或维护者，也不得是此类各方的授权代表。这不妨碍公告机构购买和使用其运营所必需的评估器械，以及进行符合性评估或为个人目的使用此类产品；

(b) 参与其指定器械的设计、制造或建造、营销、安装和使用或维护，也不得代表参与这些活动的各方。

(c) 其不得参与可能与其指定的符合性评估活动相关的判断或诚信发生冲突的任何活动；

(d) 提供可能危害其独立性、公正性或客观性置信度的任何服务。特别是，其不得向制造商、其授权代表、供应商或商业竞争对手提供有关被评估器械的设计、构造、营销、维护或评估进程的咨询服务。

(e) 与任何本身能提供如第（ d）点所述咨询服务的组织相联系。这并不妨碍对非特定客户进行与 -器械法规或标准相关的一般培训活动。

1.2.4. （员工） 在到公告机构就职时， 应充分记录其在就职前所参与的 -器械领域咨询服务，而且应根据本附录中规定的标准对潜在的利益冲突进行监管和解决。作为特定客户之前雇佣的 -或提供体 -器械领域咨询服务的人员在到公告机构就业之前，三年内不得参与该特定客户或属于相同团体的公司相关的符合性评估活动。

1.2.5. 应保证公告机构、其高层管理人员和评估人员的公正性。公告机构参与评估活动的人员、高层管理人员和分包商的薪酬水平不取决于评估结果。公告机构应公开其高层管理人员的利益申报。

1.2.6. 若公告机构由公共实体或机构拥有， 则应确保负责公告机构和 /或主管机构的国家主管机构与公告机构之间的独立性，而且这两者之间不存在任何利益冲突。

1.2.7. 公告机构应确保并记录其子公司、分包商或任何相关机构的活动，包括其所有者的活动，而且不影响其符合性评估活动的独立性、公正性或客观性。

1.2.8. 考虑到 -2003/361/EC 建议中关于费用部分所定义的中小型企业的利益，公告机构应根据一套统一、公平合理的条款和条件进行运作。

1.2.9. 本节中规定的要求绝不会妨碍公告机构和寻求符合性评估的制造商之间对技术信息和规章指南的交流。

1.3. 保密性

1.3.1. 公告机构应制定书面流程，确保其人员、委员会、子公司、分包商以及任何外部相关机构或人员在符合性评估活动执行期间遵守其所拥有信息的保密性，除非法律要求公开。

1.3.2. 公告机构人员对于根据本法规或所实施的国家法律的任何条款执行的任务所应遵守职业保密要求，除非成员国或委员会中器械方面负责的公告机构或主管机构与主管机构有关系。所有权应受到保护，公告机构应制定有关本节要求的合适的书面流程。

1.4. 责任

1.4.1. 公告机构应对其符合性评估活动办理适当的责任保险，除非根据国家法律由相关成员国承担责任，或成员国本身直接负责符合性评估。

1.4.2. 责任保险的范围和总体财务价值应与公告机构的等级和活动地理范围相对应，并与公告机构所认证器械的风险状况相称。责任保险应涵盖公告机构可能有义务取消、限制或暂停证书的情况。

1.5. 财务要求

公告机构应有在其指定范围和相关业务活动中进行符合性评估活动所需的财政资源。考虑到初始启动阶段内的具体情况，公告机构应记录并提供能证明其财政能力和长期 -经济可行性的证据。

1.6. 参与协调活动

1.6.1. 公告机构应参与或确保其评估人员获悉相关标准化活动和欧盟法规 2017/745 第 49 条中所述的公告机构协调小组的活动， 并确保评估和决定人员被告知了本法规框架内的所有相关立法、指南和最佳实践文件。

1.6.2. 公告机构应考虑到指南和最佳实践文件。

2. 质量管理要求

2.1. 公告机构应建立、记录、实施、维护和运行适当的符合性评估活动性质、区域和规模的质量管理体系，并能够支持和证明其与本法规要求的一致性。

2.2. 公告机构的质量管理体系至少应包括以下方面：

(a) 管理体系结构和文件，包括其活动的政策和目的；

(b) 有关活动分配及人员职责的政策；

(c) 根据高层管理人员和公告机构人员的任务、职责和作用进行的评估和决定过程；

(d) 计划、执行、评估和在必要时修改其符合性评估流程；

(e) 文件控制；

(f) 记录控制；

(g) 管理审查；

(h) 内部审计；

(i) 纠正与预防措施；

(j) 投诉和上诉；

(k) 持续培训。

若使用文件需要多种语言，则公告机构应确保并控制此类文件具有相同的内容。

2.3. 公告机构高层管理人员应确保整个公告机构组织（包括根据本法规参与符合性评估活动的子公司和分包商）都充分了解、实施和维护质量管理体系。

2.4. 公告机构应要求所有人员通过签字或类似形式正式承诺其会遵守公告机构规定的流程。该承诺应考虑到保密性与商业和其他利益团体的独立性以及现有或之前的有关联的客户。人员需要填写书面声明，表明其遵守保密性、独立性和公正原则。

3. 资源要求

3.1. 总则

3.1.1. 公告机构应能够以最高程度的职业操守和特定领域的必要能力来执行本法规赋予其所有任务，并且在其职责范围内无论此类任务是否有公告机构本身或代表其执行。

特别是，公告机构应拥有必要的人员，并拥有或具备在指定符合性评估活动中能够使用技术、科学和行政任务所需的所有设备、设施和权限。

该要求假定在任何时候和对于各符合性评估流程以及指定的每种类型器械，公告机构均可永久获得足够具备相关器械的知识和经验和相应技术的行政、技术和科研人员。鉴于本法规的要求，特别是附录 I 中所列的要求，应有足够数量的该人员以确保公告机构能够执行符合性评估任务，包括对已经指定的器械进行医疗功能评估、性能评估以及性能和安全性评估。

特定公告机构的能力累积必须使其能够对指定类型的器械进行评估。公告机构必须具有足够的内部能力来严格评价外部专家的评估结果。本节概述了公告机构不能转包的特殊任务。

参与公告机构对器械符合性评估活动的管理运作人员应具备适当的知识，以建立和运行一套选择评估和验证人员的系统，用于验证其授权及分配任务、初始和持续培训组织、其职责分配和监管这些员工的能力，从而确保管理和执行评估和验证的人员有能力完成其需要完成的任务。

公告机构应至少在其高层管理人员中确定一位人员，该人员对器械的符合性评估活动负全部责任。

3.1.2. 公告机构应通过建立一套经验交流、持续培训以及教育计划体系，以确保参与符合性评估活动的人员能保持其资质和专业知识。

3.1.3. 公告机构应明确记录责任范围和限制、 -人员（包括符合性评估活动中涉及的任何

分包商和外部专家）职责、和权限等级，并通知相应地人员。

3.2. 相关人员的资格标准

3.2.1. 公告机构应建立并记录资格标准和流程，以便选择和授权参与符合性评估活动的人员包括所需的知识、经验和其他能力和所需的初始和持续培训。资格标准应涉及符合性评估过程中的各种职能（例如审计、产品评估 /测试、技术文件审查、决定、批量发布）以及指定范围所涵盖的器械、技术和领域（例如生物相容性、灭菌、患者自我检测和快速诊断、伴随诊断和性能评估） 。

3.2.2. 第 3.2.1 节中所述的资格标准应根据第 38（3）条中由成员国规定的范围说明对公告机构的指定范围进行说明，并提供范围说明细分部分中所规定资格的详细信息。

应至少对以下进行特定资格标准的定义：

- 生物安全性评估、
- 性能评估
- 患者自我检测和快速诊断器械
- 伴随诊断
- 功能安全
- 软件
- 包装
- 不同类型的灭菌过程

3.2.3. 负责制定资格标准和授权其他人员进行具体符合性评估活动的人员应由公告机构雇用，而且不得是外部专家或分包商。此类人员应具备以下方面的足够知识和经验：

- 欧盟 -器械法律及相关指导性文件；
- 本法规规定的符合性评估流程；
- 器械技术的广泛知识基础，以及器械的设计和生产；
- 公告机构质量管理体系、相关流程和所需的资格标准；
- 对参与器械符合性评估活动的相关人员进行培训；
- 在满足本法规或公告机构内部先前适用法律的条件下，具有足够符合性评估的相关经验。

3.2.4. 公告机构应长期拥有具有相关临床专业知识的人员（此类人员尽可能由公告机构雇用），这些人员应在整个公告机构评估和决定过程中整合，以便：

- 确定何时需要专家投入以评估制造商进行的性能评估， 并确定合格的专家；
- 根据本法规、 CS、指南和协调标准的相关要求适当地培训外部临床专家，并确保外部临床专家充分了解所提供的评估和建议的背景和含义；
- 能够审查和科学地质疑包含在性能评估和任何相关性能研究中的临床数

据，并在由制造商提出的性能评估中适当地指导外部临床专家；

- 能够科学地评价并在必要时质疑提出的性能评估以及外部临床专家对制造商的性能评估的评定结果；
- 能够确定临床专家进行的性能评估的可比性和一致性；
- 能够对制造商性能评估和任何外部专家提供的临床判断进行评定，并向公告机构的决定者提出建议；及
- 能够制定记录和报告，以证明已执行相关符合性评估活动的正确性。

3.2.5. 负责进行产品相关审查（例如技术文件审查或型式检查，包括性能评估、生物安全性、灭菌和软件确认等方面）的人员（产品审查员）应具有以下证明资格：

- 成功获得相关专业的大学或大专学位或同等学历资格，例如，医学、制药学、工程或其他相关学科；
- 在医疗保健产品或相关活动（例如工业、审计、医疗服务、研究经验） -有四年的专业经验，同时在这些领域有两年的待评估器械或技术的设计、制造、测试或使用或相关待评估科学方面的经验；
- 具有包括附录 1中规定的通用安全与性能要求在内的关于器械法律的知识；
- 相关协调标准、 CS 和指导性文件的适当知识和经验；
- 风险管理和关于器械标准以及指导性文件的适当知识和经验；
- 性能评估相关的知识和经验；
- 与其正在评估的器械相关的知识；
- 附录 X 至 XI 中所规定符合性评估流程 （尤其在已获得授权方面） 的相关知识和经验，以及执行此类评估的足够权限。
- 能够制定记录和报告，以证明已执行相关符合性评估活动的正确性。

3.2.6. 负责对制造商的质量管理体系进行审核的人员（现场审核员）应具有以下证明资格：

— 成功获得相关专业的大学或大专学位或同等学历资格，例如，医学、制药学、工程或其他相关学科；

— 四年在医疗保健产品或相关活动的专业经验（如工业、审计、医疗保健、研究经验），同时在这些领域有两年的质量管理经验；

— 适当了解 -器械立法以及相关的协调标准、 CS（通用规范）和指导性文件；

— 风险管理和关于器械标准以及指导性文件的适当知识和经验；

— 适当了解质量管理体系和相关的 -器械标准及指导性文件；

— 附录 IX 至 XI 中所规定符合性评估流程（尤其是其负责程序）的相关知识和经验，以及执行此类评估的足够权限。

— 接受审计技术培训以便有质疑质量管理体系的能力；

— 能够制定记录和报告，以证明已执行相关符合性评估活动的正确性。

3.2.7. 负责最终审查和认证决定的人员应当是公告机构本身的雇员，而不是外部专家或分包人员。所有这些人员作为一个组，应具备以下经过考验的知识和全面经验：

— 器械法律及相关指导性文件；

— 与本法规相关的器械符合性评估；

— 与器械符合性评估相关的资格类型、经验和专业知识；

— 器械技术的广泛基础，包括正在审查的器械符合性评估的认证、器械行业和器械设计及制造的足够经验；

— 公告机构质量体系、相关流程和参与人员所需的资格；

— 能够制定记录和报告，以证明已执行符合性评估活动的正确性。

3.3. 人员资格、培训和授权的证明文件

3.3.1. 公告机构应有一个程序，以充分记录参与符合性评估活动的各人员的成员资格以及是否满足第 3.2 节中所述的资格标准。在特殊情况下，如无法充分证明是否满足第 3.2 节中规定的资格标准，公告机构应向负责公告机构的国家主管机构证明这些人员成员有权进行特定的符合性评估活动。

3.3.2. 对于第 3.2.3 到 3.2.7 节中所述的所有人员，公告机构应建立并及时更新：

— 详细说明符合性评估活动人员的授权和责任；

— 记录其获得授权的符合性评估活动所需的知识和经验的证明。记录文件应包含确定各评估人员合理的责任范围的理由和每人进行的符合性评估活动。

3.4. 分包商和外部专家

3.4.1. 在不影响第 3.2 节的限制的情况下，公告机构可转包符合性评估活动中某些定义明确的部分。

不允许对整个质量管理体系或产品检验相关的审核进行分包，但是这些活动的某些部分可由分包商和外部审核员以及专家代表公告机构执行。公告机构保留全部责任，以便能够提供适当的证据证明分包商和专家能够履行其特定任务，保留根据分包商的评估做出决定，并对分包商和专家代表其进行的工作。

以下活动不得由公告机构转包：

— 对外部专家的资格审查和行为监管；

— 审计或认证组织的分包审计及认证活动；

— 将工作分配给外部专家进行具体的符合性评估活动；

— 最终审查和决定职能。

3.4.2. 若公告机构将某些符合性评估活动分包给某个组织或个人，则应有一个说明允许进行分包的条件的政策，并应确保：

— 分包商符合本附录的有关规定；

— 分包商和外部专家不再将工作转包给组织或人员；

— 关于所述的第一行和第二行缩进的要求已经告知申请符合性评估的自然人或法人

外部人员的任何分包或咨询应有适当的文件记录且不得涉及任何中间人，并应遵守直接的书面协议，其中包括保密性和利益冲突。所述的公告机构应对分包商完成的任务承担全部责任。

3.4.3. 若在符合性评估的背景下使用分包商或外部专家，特别是关于新的器械或技术，所述的公告机构应在各产品领域具有足够领导整体符合性评估的能力，以验证专家意见的适当性和有效性，并对认证做出决定。

3.5. 监测能力、培训和经验交流

3.5.1. 公告机构应制定流程，对符合性评估活动中涉及的所有内部和外部人员和分包商的能力，符合性评估活动和绩效进行初步评估和持续监测。

3.5.2. 公告机构应定期审查其人员的能力，确定培训需求，并制定培训计划，以保持人员所需的资格和知识水平。本审查至少应验证人员：

— 是否了解当前体外诊断医疗器械法规、相关协调标准、 CS（通用规范）、指导文件和第 1.6 节中所述的协调结果；

— 根据第 3.1.2.节参与内部交流经验和持续培训及教育计划。

4. 程序要求

4.1. 总则

公告机构应有指定的各符合性评估活动的书面流程和足够详细的流程，包括从预申请活动到决定及监督的各个步骤，并在必要时考虑到器械的相应特性。

第 4.3、 4.4、 4.7 和 4.8 节所述的要求应为公告机构的内部活动，不得分包。

4.2. 公告机构报价和预申请活动

公告机构应

(a) 发布公开可用的申请程序说明，以便制造商从其获得认证。该说明应包括提交相关文件可使用的语言，

(b) 对特定符合性评估活动所收取的费用以及其他与公告机构器械评估活动相

关的财务条件应有详细的书面流程,

(c) 有关于符合性评估服务广告的书面流程。这些书面流程应确保广告或促销活动绝不暗示制造商或可能导致符合性评估提前获批进入市场，或者比其他公告机构更快、更容易或更不严格,

(d) 有关于审查预申请信息的书面流程，包括在本法规所涵盖产品的初步验证及其分类，然后向制造商发出关于特定符合性评估的报价,

(e) 确保与本法规所涵盖的符合性评估活动有关的所有合同都直接在制造商和公告机构之间签订，而不是与任何其他组织签订。

4.3. 申请审查与合同

公告机构应要求（申请人）提供由制造商或授权代表签署的正式申请，其中应包含相关符合性评估附录 IX 至 XI 中所述的所有信息和制造商的声明。

公告机构与制造商之间的合同应采取双方签署的书面协议的形式。其应由公告机构保存。本合同应有明确的条款和条件，并包含使公告机构能够按照本法规的要求行事的义务，包括制造商有义务通知公告机构警戒报告，公告机构有权暂停、限制或取消发放的证书以及公告机构履行其信息义务的义务。

公告机构应有关于审查申请的书面流程，以便处理：

(a) 关于在相应附录中所述的已获批准的这些有关符合性评估流程要求申请的完整性,

(b) 这些申请所覆盖产品器械及其各自分类的资格验证,

(c) 无论申请人选择的符合性评估程序是否适用本所述法规中的器械 -,

(d) 公告机构根据其委任来审核申请表的能力,

(e) 充足和适当资源的可用性。

各申请审查的结果应记录在案。拒绝或撤销的申请应通知第 52 条中所述的电子系统，其他指定机构应当有权访问相关数据。

4.4. 资源分配

公告机构应有书面流程，以确保所有符合性评估活动由经过适当授权和合格的人员进行，这些人员应具有足够的经验以对需要进行符合性评估的器械、系统和过程以及相关文档进行评估。

对于各应用，公告机构应确定资源需求，并指定某个人负责确保各应用的评估都根据相关流程进行并确保适当资源包括人员在评估的，各任务中的可用性。应进行任务分配作为要求的符合性评估部分以及随后对此分配所做的任何更改都应记录在案。

4.5. 符合性评估活动

4.5.1. 总则

公告机构及其人员应进行具有最高专业素质的符合性评估活动，并具备特定领域必要的技术和科学能力。

公告机构应具有足够的专业知识、设施和详细的文件化流程，以有效地进行所所述公告机构指定的符合性评估活动，同时要考虑到本法规附录 IX 至 XI 中列出的相关要求，尤其是以下要求：

— 适当规划各独立项目的行为；这些机构

— 应确保所组成的评估小组有相关技术经验，持续的客观性，及独立性，其中应包括规定在适当的时间轮换评估小组成员，

— 说明符合性评估活动完成时限确定的合理性，

— 评估制造商的技术文件及为满足附录 I 所列要求而采用的解决方案，

— 审查制造商的与性能评估相关的流程和文件，

— 定位制造商风险管理程序及其性能评估的评定和分析之间的界面，以评估符合性证明与附录 I 有关要求的相关性，

— 执行附录 IX 第 5 节中所述的“特定流程”，

— 对于 B 类或 C 类器械，基于典型性原则评估技术文件，

— 计划和定期进行适当的监管审核和评估，执行或要求执行特定测试，以验证质量管理体系的正常运作，并进行未事先通知的现场审核，

— 若涉及器械采样以验证制造的器械符合技术文件，该要求应在采样前定义相关的采样标准和测试程序，

— 评估和验证制造商的活动是否符合相关附录的要求。

公告机构必要时应考虑可用的 CS、指导文件、 最佳实施文件和协调性标准， 即使制造商未声明符合性。

4.5.2. 质量管理体系审核

(a) 作为质量管理体系评估的一部分， 公告机构应在审核之前根据其书面流程：

— 评估根据相关符合性评估附录提交的文件并建立一个审核程序， 该程序应清楚定义能完全覆盖制造商质量管理体系核查所需的评估活动的数量及顺序，并确定其是否符合本法规的要求，

— 确定制造商不同生产地址之间的联系和分配责任， 以及确定相关的制造商供应商和 /或分包商 -，包括考虑是否需要对这些供应商和 /或分包商或供应商和分包商两者进行专门审核，

— 为审核程序中确定的每项审核， 明确界定审核目标、 标准和范围， 并拟订一份审核计划， 以充分解决并考虑所涉器械、 技术和过程的特殊需求，

— 为 B 类和 C 类器械建立一份抽样计划并保持更新，以评价依据附录

II 所述的技术文件且技术文件应涵盖制造商所申请的器械，该计划应确保证书效期内所涵盖的所有器械均有抽样，

— 选择和指派适当的有资质被授权人员进行独立审核。应清楚地定义并记录下团队成员各自的职位、职责和权限。

(b) 基于建立的审核程序，公告机构应根据其书面流程：

— 审核制造商的质量管理体系，以验证确保所涵盖的器械符合本法规的有关条款（这些条款适用于器械从设计到最终检查及持续监控的各阶段）的质量管理体系，同时确定是否满足本法规的要求，

— 基于相关技术文件以确定制造商是否符合相关符合性评估附录要求，审查和审核制造商过程和子系统，尤其是：

— 设计及开发

— 生产过程控制

— 产品文档

— 采购控制（含所采购器械验证）

— 纠正预防措施（含上市后监管）

— PMPF

— 审查和审核制造商采用的要求和规定，包括这些在附录 I 中规定的用于实现通用安全和性能安全的要求和规定

— 应对文档进行抽样，并以这样一种方式进行，即反应与器械预期用途相关的风险、制造技术的复杂性、所生产器械的范围和类别及任何适用的上市后监控信息

— 若尚未被审核程序覆盖，且成品器械的符合性被供应商的动作显著影响，特别是制造商不能证明其对供应商的充分控制时，则需对生产者供应商场所的流程控制进行审核

— 基于其抽样计划并参照本附录中关于性能评估的第 4.5.4. 节的内容，对技术文件实施评价。

— 公告机构应确保审核结果是根据本法规或及 MDCG 制定并采纳的相关标准或最佳实施文件，被恰当并一致地归类的。

4.5.3. 产品验证

技术文件评估

为评估依据附录 IX 第 II 章而执行的技术文件，公告机构应具有充分的专业知识、设施、并为以下情形提供详细的书面流程：

— 对具有相应资质并获得授权人员的分配，以执行各个方面检验（如器械使用、生物相容性、性能评估、风险管理和灭菌），

— 依照本法规评估设计符合性并考虑 4.5.4. 节和第 4.5.5. 节规定，这种评估应包括对新进的、过程中的和最终的检查的执行情况和结果的检查。如需进

一步检测或其他证据，以评估其是否符合本法规的要求，所所述公告机构应当实施与器械有关的充足的物理或实验室测试，或要求制造商实施这些测试。

型式检查

公告机构应具有按照附录 X 进行器械型式检查的详细书面流程、 充分专业知识和设施，包括以下能力：

— 依照本附录第 4.5.4.节和第 4.5.5.节检查和评估技术文件，并验证制造类型是否符合技术文件。

— 建立一个测试计划，确定公告机构需要测试或在其职责范围之内的所有相关和关键参数。

— 记录选择这些参数的理由。

— 进行适当的检验和测试，以验证制造商采用的解决方案是否满足附录 I 规定的通用安全与性能要求。该检查和测试应该包括所有必要的测试，以验证该制造商实际上已遵守相关标准，选择它用于。

— 若公告机构不直接进行这些测试，则需要与申请人协定必要测试的执行地点。

— 对测试结果承担全部责任。可考虑制造商提交的测试报告，若它们由具有资质以及独立于制造商的符合性评估机构颁发。

通过检查和测试每批产品进行验证，公告机构应该：

(a) 具有详细书面流程、 充分专业知识和设施， 以通过按照附录 VIII 和附录 IX 检查和测试每批产品进行验证；

(b) 建立一个检测计划，确定公告机构需要检测的，或在其职责范围之内的所有相关和关键参数，以便：

- 对于 C 类器械，验证这些器械是否符合欧盟型式检查证书说明的类型和本法规中适用要求，

- 对于 B 类器械，确认是否符合附录 II 和附录 III 中所述的技术文件和本法规中适用要求，

(c) 并记录选择第（ b）点中参数的理由。

(d) 具有书面流程以进行适当的评估和测试， 检查和测试如附录 XI 第 5 节中所述的每批产品，从而验证器械是否符合本法规的要求；

(e) 若公告机构本身不直接执行这些必要测试，则应与申请者就这些必要测试在何时及哪里进行检测达成一致，并生成书面流程；

(f) 按照书面流程，对测试结果承担全部责任。仅接受制造商提交的由具有资质且独立于制造商的符合性评估机构颁发的检测报告。

4.5.4. 性能评估的评定

公告机构对流程和文件的评估应着眼于文献检索结果，及所有的验证、确认和进

行地检测和结论，同时还应考虑使用可选材料和物质、包装、稳定性（包括成品器械的有效期）等方面。若制造商没有进行新的检测或背离了流程，所所述公告机构应适当质疑制造商的理由。

公告机构应持有对制造商产品性能评估相关的流程及文件进行评估的相关书面流程，这些文件即为最初的符合性评估，又是持续的基础。公告机构应充分地检查、验证和确认制造商的流程和文件于以下方面：

(a) 根据附录 XIII 进行的性能评估的计划、实施、评估、报告和更新，

(b) 上市后监管和上市后性能跟踪，

(c) 与风险管理流程的相互作用，

(d) 可用数据及其相关性的分析和评估，以证明其符合附录 I 的相关要求，

(e) 根据性能评估报告中的临床证据及成果而得出的结论。

这些在第二段中的流程应考虑到现有 CS、指导原则和最佳实施文件。

根据附录 XIII ，公告机构的性能评估的评定应包括：

— 制造商确定的预期用途，及其定义的器械宣称，

— 性能评估计划，

— 文献检索方法，

— 文献检索有关文件，

— 性能研究，

— 上市后监管和上市后性能追踪，

— 与相关其他器械等同性声明的有效性，等同性证明，等同及类似器械的适用性及结论资料，

— 性能评估报告。

— 相关未执行的性能研究或 PMPF 的说明

关于性能评估中的性能研究资料，鉴于这些批准的性能研究研究计划，所所述的公告机构应确保制造商得出的结论是有效的。

公告机构应确保性能评估充分着眼于附录 I 中规定的安全与性能相关要求，并适当地与风险管理保持一致，按照附录 XIII 执行且恰当地反映在所提供的器械相关信息之中。

4.5.5. “特殊流程”

针对附录 XI 的第 5 节委任给公告机构的流程，公告机构应有相应的书面程序、足够的专业知识和设施。

在伴随诊断的情况下，公告机构应具有旨在实现本法规要求的相关书面流程，以用于在该类型器械评估过程中咨询欧盟医药管理局或医药产品主管机构。

4.6. 报告

公告机构应：

— 确保记录了符合性评估中的所有步骤，使得这些评估结论明确并证明其符合本法规的要求，并为那些未亲自参与评估的人提供客观证据，如指定授权机构的工作人员，

— 确保记录足以提供一个清晰的审核线索并可用于质量管理体系，

— 在性能评估考核报告里清楚地记录其性能评估考核结论，

— 对各具体项目，提供一份详细报告，报告应基于标准格式，内容应至少需包含 MDCG 的决议。

公告机构报告应：

— 对于验证制造商是否严格遵照本法规要求执行，清楚地记录其评估结果，给出明确结论，

— 公告机构给出最终审查建议和最终决定；该建议应 -由公告机构的负责人员成员签署，

— 并提供给所所述的制造商。

4.7. 最终审查

在做出最后决定之前，公告机构应确保：

— 对于负责特定项目的最终审查和决定工作的人员应慎重选派，且不可与评估执行人员为同一人，

— 验证做出决定所需的报告和支持文件，包括有关评估过程中对所申请范围内容提出的不符合项，

— 验证是否存在任何悬而未决的、阻止欧盟证书签发的不符合项。

4.8. 决定和证书

对于决定的做出，公告机构应具有书面流程，包括有关证书的签发、中止、限制和撤销的责任分配。这些流程应包括本法规第 V 章中规定的公告要求。该流程应允许所所述公告机构：

— 决基于评估文件和可用的附加信息，决议申请者是否满足本法规要求，

— 若是上市后监管计划，基于其性能评估考核和风险管理结果做出决议，包括决议 PMPF 是否充分，以及在性能评估资料阶段性更新的前提下公告机构可做出是否需要进一步审查的决议

— 决定是否需要在证书上定义特定的条件或条款，

— 基于创新性、风险等级分类、性能评估及器械风险分析的结果，决议证书期限不超过五年，

— 清楚地记录决定和审批的各步骤，应包括相关负责人员成员的签字批准，

— 清楚地记录决定协商机制和权责，特别是当证书的最终签署者与决策者不同或不符合第 3.2.7 节中规定的要求时，

— 根据附录 XII 的最低要求，颁发证书的有效期不得超过五年，并如有附加特定条件或限制应在证书上注明，

— 仅为申请人颁发证书，不得为多个实体颁发证书，

— 确保将评估结果和最终决定通知制造商，并录入第 52 条中所述的电力系统。

4.9. 变更和修改

若涉及以下信息变化，公告机构和制造商之间应依照适当的书面流程和合同安排来行使责任并进行相关评估：

— 经批准的质量管理体系或所覆盖的产品范围，

— 经批准的器械设计，

— 经批准的器械类型，

— 器械所包含的或用于器械生产的任何物质，属于第 4.5.5 节“特殊流程”中规定的情形。

这些在第一段中所述的流程和合同安排应包括第一段中所述的检查变更重大程度的过程。

根据其书面流程，所所述的公告机构应：

— 在做出批准之前，确保制造商提交第一段中所述的变更计划以及与变化相关的信息，

— 对申请的变化进行评估，并验证变更后的质量管理体系或器械设计或器械类型是否仍能符合本法规的要求，

— 将其决定通知制造商并提供一份报告作为补充报告，其中应包含其评估/审核的合理结论。

4.10. 监管活动和认证后监控

公告机构应设定书面流程，包括：

— 确定何时以及以何种方式对制造商采取监管活动。

这些流程应包括对制造商及分包商和供应商（如适用），进行突击现场审核，产品检验，并监控制造商是否符合认证决定所涉及的相关条件，例如，在规定时间间隔内的临床数据更新，

— 对于筛查科学和临床数据的相关来源，及其功能设计相关范围内的上市后信息。在计划和开展监管活动时，应考虑此类信息，

— 审查可根据第 87 条获取的警示信息，以便估计其对现证书有效性的影响（如有）。评估结果和做出的任何决定，都应全面记录。

所所述的公告机构一旦来自制造商或主管机构的警示案件信息之后，应决定是否采取如下行动措施：

— 无需采取行动，因为警示案件与已颁发的证书明显无关联，

— 观察制造商和主管机构的活动，以及制造商的调查结果，以确定对于已颁发的证书是否无影响到或已经执行适当的纠正措施，

— 若影响到已颁发的证书，需执行特殊监管措施（如文件审查、临时通知的或无告知的突击审核、产品检测等），

— 提高监管审核频率，

— 在对制造商的下一次审核中，审查特定产品或流程，或

— 采取任何其他相关措施。

关于制造商的监管审核，公告机构应设立书面流程，包括：

— 对制造商至少每年进行一次监管审核，且该计划和实施应符合第 4.5.节中的相关要求，

— 确保充分评估制造商针对警示条款、上市后监管和 PMPF，

— 在审核期间，检测仪器、样本及其技术文件，应根据预先确定的采样标准和检测流程执行，以确保制造商始终符合经批准的质量管理体系，

— 确保制造商符合相关附录所规定的文件要求和信息责任，并考虑制造商是否按照质量管理体系的最佳实施流程来执行，

— 避免制造商不按规定执行质量管理体系或避免器械审批出现失误，

— 收集充分的信息，以确定质量管理体系是否持续符合本法规的要求，

— 若检测到不符合项，应要求制造商进行整改，采取纠正预防措施（如适用），且

— 必要时，对相关证书施加特殊的限制或中止或撤销。

如属于证书限制条件的一部分，该公告机构应：

— 基于制造商的上市后监管、其 PMPF、相关使用器械治疗适应症的临床文献或同类器械产品的临床文献，对制造商的最新更新的性能评估进行深入审查，

— 清晰记录本次审查结果，并对制造商提出的任何具体问题或情况进行解答，

— 确保最新更新的性能评估恰当地反映在产品使用说明书，以及安全与性能数据摘要中（如适合）。

4.11. 再认证

关于再认证审查和证书的更新，公告机构应具有适当的书面流程。应至少每五年对批准的质量管理体系，或欧盟技术文档评估证书，或欧盟型式检查证书进行一次再认证。

对于欧盟技术文档评估证书和欧盟型式检查更新，公告机构应具有相关书面流程，这些证书和流程应要求所所述制造商对该器械做出的更改及的科学发现提交一份摘要，包括：

(a) 对原批准器械做出的所有更改，包括尚未认证的更改，

(b) 从上市后监管获取的经验，

(c) 从风险管理获取的经验,

(d) 从通用安全与附录 I 中规定的性能要求符合性证据的更新而获取的经验,

(e) 从性能评估审查获取的经验，包括任何性能研究和 PMPF 的结果,

(f) 任何性能要求的变化、器械组成的变化、以及科学或法规环境的变化,

(g) 已经采用的或新（协调）标准发生变化, CS 或同等文件的变化,

(h) 医疗、科学和技术知识的变化，例如：

— 新疗法,

— 检测方法的变化,

— 材料、组成的新科学发现，包括其生物相容性方面的发现,

— 从同类器械市场研究获取的经验,

— 注册人及注册信息,

— 从同类器械性能研究获取的经验。

公告机构应具有第二段中所述的书面流程，以评估这些信息，并且应特别注意自前次认证或再认证至今，从上市后监管和 PMPF 活动得到的临床数据，其中包括制造商的性能评估报告的适当更新。

对于再验证的决定，所所述的公告机构应采用与最初决定相同的方法和原则。如必要，应建立单独的表格用于在认证，并考虑认证所采取的步骤，如申请和申请审核。

附录 **VIII**

分类规则

1. 实施规则

1.1. 分类规则的使用应基于器械的预期目的。

1.2. 若该器械将与其他器械共同使用，分类规则应分别适用于各器械。

1.3. 对于在体外诊断医疗器械中的附件应与其配合使用的器械分开单独进行分类。

1.4. 驱动某一器械或影响器械使用的软件，应与该器械归为同一类别。若该软件独立于任何其他器械，则按照其本身进行分类。

1.5. 预期与某一器械配合使用的校准品，应与该器械归为同一类别。

1.6. 赋值质控品包括定量和定性质控品，用于某一特定分析物或多种分析物的赋值质控品应与该器械归为同一类别。

1.7. 制造商应考虑所有分类和实施规则，便于为器械确定正确的分类级别。

1.8. 若制造商声称某个器械具有多种预期用途，使得该器械可归为多个类别，则它应被归入较高的类别。

1.9. 若多个分类规则适用于同一器械，产品类别以最高的为准。

1.10. 每条分类规则适用于一线试剂、确认试剂和补充试剂。

2. 分类规划

2.1. 规则 **1**

用于以下用途的器械归类为 D 类：

— 检测血液、血液成分、细胞、组织或器官，或其任何衍生物是否存在或显露传染性因子，以评估它们是否适用于输血、器官移植或细胞给药。

— 检测是否存在或显露传染性因子，其会导致危及生命的疾病，并且具有高的或可疑的传播风险。—确定危及生命的疾病的病原体载量，其监控对于患者管理的过程十分关键。

2.2. 规则 **2**

器械预期用于血型分型或组织分型，以确保用于输血或移植或细胞给药的血液、血液成分、细胞、组织或器官具有免疫相容性，此类器械归类为 C 类，但用于确定以下任何标记物的器械除外：

— ABO 系统 [A（ABO1）、B（ABO2）、AB（ABO 3）]；

— 恒河猴（ Rhesus）系统 [RH1（D）、RHW1 、RH2（C）、RH3（E）、RH4（C）、RH5（E）]；

— KELL 系统 [Kel1（K）]；

— KIDD 系统 [JK1（JKA）、JK2（JKB）]；

— DUFFY 系统 [FY1（FYA）、FY2（FYB）],

在这种情况下，它们被归为 D 类。

2.3. 规则 **3**

器械被归为 C 类，若其目的是：

(a) 用于检测是否存在或显露性传播病原体的；

(b) 用于检测是否在脑脊液或血液中存在某种高的或可疑的高传播风险的病原体；

(c) 用于检测病原体的存在，其报告结果若错误可带来引起个人、胎儿、胚胎或个体的后代死亡或严重残疾的重大风险；

(d) 用于女性的产前筛查，确定其对感染原的免疫状况；

(e) 用于确定感染性疾病的状态或免疫状态，若其报告结果将会引起患者治疗决定导致危及患者或患者后代生命的风险；

(f) 用作伴随诊断；

(g) 用于疾病分期，若其报告结果错误将会引起患者治疗决定导致危及患者或患者后代生命风险的；

(h) 用于癌症的筛查、诊断或分期；

(i) 人类基因检测；

(j) 用于检测药用产品、物质或生物组分的水平，若其报告结果错误将会引起患者治疗决定导致危及患者后代生命的风险；

(k) 对危及生命的疾病或病症患者，进行患者管理；

(l) 用于筛查胚胎或胎儿的先天性疾病；

(m) 用于新生儿的先天性疾病筛查，未能检测和治疗这些疾病可能导致危及生命的情况或严重残疾。

2.4. 规则 **4**

(a) 自测器械归为 **C** 类，但用于妊娠检测、生育力测试、确定胆固醇浓度以及检测葡萄糖、红细胞、白细胞和尿样本中细菌的器械除外，这些器械归为 **B** 类。

(b) 床旁检测器械根据其本身特性进行分类。

2.5. 规则 **5**

以下器械归为 A 类：

(a) 一般实验室使用的产品、没有危险特征的附件、缓冲液、洗涤液、一般培养基和组织学染色液，制造商使其适用于相关某一特定检查的体外诊断流程；

(b) 制造商专门用于体外诊断流程的器械；

(c) 样品容器。

2.6. 规则 **6**

上述分类规则未涵盖的器械归类为 **B** 类。

2.7. 规则 **7**

不具有定量或定性赋值的质控品的器械归类为 **B** 类。

附录 IX

基于质量管理体系和技术文件评估的符合性评估

第 I 章：

质量管理体系

1. 如本法规第 10（8）条所述，制造商应建立、记录和实施质量管理体系，并保持其在相关器械的整个生命周期内的有效性。制造商应确保质量管理体系的运行，如第 2 节规定；根据第 2.3 和 2.4 节的规定进行审核，并且根据第 3 节规定进行监管。

2. 质量管理体系评估

2.1 制造商应向公告机构提出申请，评估自己的质量管理体系。申请应当包括：

- 质量管理体系所覆盖的制造商名称及其他生产场所的所在地的注册名称和地址，若制造商申请由其授权代表提出，同时也需要给出授权代表姓名及其所在地注册的地址，
- 质量管理体系覆盖的器械或器械组的所有相关信息，
- 一份书面声明，表明没有向其他公告机构，就同一器械相关的质量管理体系提交申请，或给出同一器械相关的质量管理体系以往的信息，
- 一份依据第 17 条和附录 III 的欧盟符合性声明的草稿，针对符合性评估流程所覆盖的器械型号
- 质量管理体系文件，
- 一份相关流程的书面说明，其中包括履行质量管理体系中提出的义务及根据本法规要求，以及制造商对使用这些流程的保证，
- 一份相关流程的说明，以保持质量管理体系能保持正确性和有效性，以及相关制造商对使用这些流程的保证，
- 制造商上市后监管体系的文档以及适用的 PMPF 计划和流程以保证其符合第 82 条至 87 条警戒规定的义务，
- 一份相关流程的说明，以保持最新的上市后监管体系以及适用 PMPF 计划和流程以保证其符合第 82 条至 87 条警戒规定的义务，以及制造商对使用这些流程的保证，
- 性能评估计划的文件，
- 一份相关流程的说明，以保持性能评估计划的更新，并考虑目前工艺水平。

2.2 质量管理体系的实施应确保遵守本法规规定。制造商为其质量管理体系而采用的所有要素、要求和规定，必须以系统和有序的方式记录在质量手册、书面政策和程序之中，例如质量流程、质量计划和质量记录。

此外，为质量管理体系的评估而提交的文件应包括适当的说明，特别是：

(a) 制造商的质量目标；

(b) 业务的组织，特别是：

- 组织结构，分配与关键流程有关的工作人员责任、管理人员的职责和其组织权力，

- 监管质量管理体系是否有效运行的方法，特别是该体系实现预期的设计和器械质量的能力，包括控制那些未符合要求的器械，

- 器械的设计、 制造和 /或最终验证和测试，或任何程序的任何部件， 由另一方承担，质量管理体系有效运行的监管方法，特别是对其中一方施加的控制类型和程度，

- 若制造商在某个成员国没有注册营业地址，需提供一份授权草稿，任命一位授权代表，并且授权代表出具意向书，愿意接收这个授权；

(c) 用于监控、 验证、 确认和控制器械设计的流程和技术， 相应的文件以及这些流程和技术所产生的数据和记录，这些流程和技术应包括以下内容：

- 法规符合性策略，包括确定相关法律要求、资质、分类、等效性处理、符合性评估流程的选取和遵守的过程，

- 确定适用的通用安全与性能要求以及解决这些问题的方案符合上述要求，同时考虑适用的 CS 和协调的标准或等同解决方案，

- 附录 I 第 3 节所述的风险管理，

- 性能评估，根据第 56 条和附录 XII 的规定，包括 PMDF ，

- 对于设计和构造，满足适用的具体要求，其解决方案包括适当的临床前评估，特别针对附录 I 第 II 章规定要求，

- 对于和器械一同提供的信息，满足适用的具体要求的解决方案，特别针对附录 I 第 III 章规定要求，

- 草拟器械识别流程，在生产的每一个阶段，与图纸、规范或其他相关文件保持同步

- 设计的管理或质量管理体系的变更；

(d) 生产环节的验证和质量保证技术， 特别是将要使用的过程和流程 （尤其是在面具方面）及相关文件，

(e) 制造前、 制造中和制造后将要实施的适用的测试和试验， 其发生的频率和待使用的测试器械，并应能充分地追溯测试器械的校准情况。

此外，制造商应给予公告机构权利，获取附录 II 和 III 所述的技术文件。

2.3. 审核

公告机构应审核质量管理体系，以确定它是否满足第 2.2 节中所述的要求。关于质量管理体系，若制造商使用了协调标准或 CS，则公告机构应符合这些标准或 CS。除非有充分证据证明，否则公告机构应就满足相关协调标准或 CS 的质量管理体系，假设其符合这些标准或 CS 涵盖的要求。

根据附录 VI 的第 4.4 节至第 4.5 节，公告机构的审核小组应至少包括一位具有相关技术评估经验的成员。若这种经验不直观或不适用，公告机构应该提供组成该审核小组的书面理由。评估流程应包括，基于制造商而做出的审核，如适用，应基于制造商的供应商和/或分包商，以验证制造和其他相关过程。

此外，若器械是 C 类器械，质量管理体系评估应伴随着器械技术文件的评估，按照第 4.4 至第 4.8 节的规定，器械的选择应具有代表性。在选择代表性样本的过程中，公告机构应考虑 MDCG 根据第 99 条而设计和发布的准则，特别是技术的创新性、对患者和标准医疗实践的潜在影响、设计、技术和制造的相似性，以及适用的灭菌方法、预期目的和之前根据本法规而执行的任何相关评估的结果。相关公告机构应记录其样品选择的理由。

若质量管理体系符合本法规的有关规定，公告机构将出具的欧盟质量管理体系证书。且公告机构应通知制造商其颁发证书的决定。它应包括审核结论和理由报告。

2.4. 相关制造商应通知公告机构（批准制造商的质量管理体系），其质量管理体系的任何重大变化计划，或涵盖的器械范围的变化。公告机构应评估拟定的修改，确定是否需要额外的审核，并核实这些更改后的质量管理体系是否仍符合第 2.2 节所述的要求。应该将其决定通知制造商，决议包括评估结论，或在适用情况下，额外审核的结论。
对于质量管理体系或器械覆盖范围的重大改变，其批准过程应采取欧盟质量管理体系证书的补充形式。

3. 适用于 **C** 类和 **D** 类器械的监管评估

3.1. 监管目的是确保制造商充分履行批准后的质量管理体系所规定的义务。

3.2. 制造商应授权公告机构进行所有必要的审核，包括现场审核，并提供所有相关信息，特别是：

- 质量管理体系的文件；
- 使用上市后监管计划而获取的任何调查结果和结论，包括对具有代表性的器械，进行 PMPF 计划，以及第 82 至第 87 条所述的警戒规定，
- 与设计相关的质量管理体系部分所规定的数据，例如分析、计算、试验的结果以及针对附录 I 第 4 节所述风险管理所采用的解决方案，
- 与制造相关的质量管理体系部分所规定的数据，例如，质量控制报告和试验数

据、校准数据、相关人员的资质报告等。

3.3 公告机构应定期，至少每隔 12 月开展一次，适当的审核和评估，以确保相关制造商采用批准的质量管理体系和上市后监管计划。 审核和评估应包括对制造商经营场所的审核，必要时，还包括对制造商的供应商和/或分包商经营场所的审核。如有必要，在进行现场审核时，公告机构应进行或要求进行试验，以便检查质量管理体系是否恰当发挥了作用。并应为制造商提供监管审核报告。 若已进行试验，则其应为制造商提供试验报告。

3.4 公告机构应至少每隔五年随机对制造商进行一次现场突击审核，必要时，还应对制造商的现有供应商和/或分包商进行此类现场审核，并可结合第 3.3 节所述的定期监管评估或进行该监管评估以外的评估。 公告机构应制定此类现场突击审核的计划，但不得向制造商披露。

在进行此类现场突击审核时，公告机构应选取测试生产器械或制造过程中的足够样品进行试验，以验证所制造的器械是否符合技术文件的要求。在进行现场突击审核前，公告机构应规定相关取样标准和检验程序。

除了进行第 2 项所述的取样以外，公告机构还应进行器械的市场取样，以验证所制造的器械是否符合技术文件的要求。在取样前，相关公告机构应规定相关取样标准和检验程序。

公告机构应为相关制造商提供现场审核报告，如适用，其中还应包括样品试验的结果。

3.5. C 类器械的监管评估还应包括评估第 4.4 至 4.8 节所述的相关器械技术文件。评估需基于更具代表性的样品选取。 而这些样品的选择依据是公告机构根据第 2.3 节第 3 项所述之基本原理。

3.6. 公告机构应确保审核小组的成员具备器械、系统以及相关工艺的评估经验，且其评估具有持续的客观性和中立性，这应包括评估小组成员以适当的时间间隔轮流进行评估。一般而言，审核组组长连续领导和参与审核同一制造商的时间均不得超过三年。

3.7. 若公告机构发现生产样品或市场样品与技术文件或批准设计所规定的规范之间存在差异，则应吊销或撤销相关证书或对其施加限制。

第 II 章

技术文件评估

4. 适用于 **B**、**C** 和 **D** 类器械的器械技术文件评估和批次验证

4.1. 除了第 2 节所规定的义务以外，D 类器械的制造商还应向公告机构申请进行相关器械技术文件评估。 这些器械包括制造商计划出售或交付使用的器械以及第 2 节所述质量管理体系所涵盖的器械。

4.2. 申请书应说明相关器械的设计、制造和性能。 其应包括附录 II 和 III 中所述的技术文

件。

对于自测或床旁检测所用的器械，申请书中还应包括第 5.1 节 b 点所述的方面内容。

4.3. 公告机构应利用技术评价、相关器械评价以及临床证据评价方面的公认知识和经验来审查职员聘任申请书。公告机构可要求提供根据进一步试验或其他证据所填写的申请书，以使评估符合本法规的相关要求。公告机构应进行与器械相关的充分的物理或实验室试验，或要求制造商进行此类试验。

4.4. 根据公告机构应专门审查制造商所递交性能评价报告和相关性能评价中的临床证据。就该审查而言，公告机构应使用聘任的临床专业知识丰富的器械审查员，包括具有相关器械临床应用方面直接和现有经验的外部临床专家。

4.5. 若临床证据全部或部分基于所公布器械的数据，且这些器械与所评估的器械相似或相同，则公告机构应评估使用此类数据的适用性，并考虑新趋势和创新等因素。公告机构应明确记录其对于所公布数据等效性，以及相关性和充分性的结论，以证明数据符合要求。

4.6. 公告机构应验证临床证据和性能评价是否充分，并验证制造商所得出的结论是否符合通用安全与性能要求。该验证应包括考虑分析与收益评估充分性、风险管理、使用说明书、 使用者培训、 制造商的上市后监管计划， 如适用，还应包括审查拟定 PMPF 计划的必要性和充分性。

4.7. 根据其对产品临床证据的评价，公告机构应考虑性能评估、及风险与收益的综合评估以及是否需要确定特定节点，以便公告机构根据上市后监管和 PMPF 数据对更新的临床证据进行审查。

4.8 公告机构应在性能评估的评定报告中明确记录其评价结果。

4.9. 在颁发 EU 技术文件评估证书前， 公告机构应要求根据第 100 条所指定的参考实验室验证制造商所公布的性能， 如适用， 还应要求其验证器械对 CS 或制造商所选定其他解决方案的符合性，以确保保持一定的安全等级和至少等同的性能。验证应包括按照第 48（5）条所述在 EU 参考实验室进行的实验室试验。

此外，对于本法规第 48（6）条所述的情况，公告机构应按照第 48（6）条所规定的关于制造商性能评价报告的程序，咨询欧盟第 2017/745 号法规第 106 条所述的相关专家。

EU 参考实验室应在 60 天内提出科学性意见。

公告机构的相关器械文件中应包括 EU 参考实验室的科学性意见， 在适当情况下， 根据第 48（6）条所规定的程序，咨询专家的看法。公告机构在做出决定时应适当考虑 EU 参考实验室所提出的科学意见，如适用，还应适当考虑根据第 48（6）条咨询专家明确提出的看法。若参考实验室的科学性意见是反对的，则公告机构不得颁发证

书。

公告机构应为制造商提供技术文件评价报告，包括性能评估的评定报告。若器械符合本法规的相关规定，则公告机构应颁发 EU 技术文件评估证书。

4.10. 证书应包含技术文件评估结论、证书批准条件、可识别批准器械的数据，若适合，还应包含器械预期用途的说明。

4.11. 若已批准器械发生会影响器械安全与性能的变更或器械的使用条件发生变更，则这些变更需要获得颁发 EU 技术文件评估证书的公告机构的批准。若制造商计划进行任何上述变更，则其应通知本文件所述颁发 EU 技术文件评估证书的公告机构。公告机构应评估申请的变更并确定是否需要根据第 48 条对申请的变更重新进行符合性评估，或是否可通过 EU 技术文件评估证书的附录的形式予以说明。对于后者的情况，公告机构应评估变更，并将其决定告知制造商，且若这些变更获得批准，则公告机构还应为制造商提供 EU 技术文件评估证书的附录。

若这些变更会影响器械对 CS 或制造商所选定且 EU 技术文件评估证书所批准的其他解决方案的符合性，则公告机构应咨询前述咨询所涉及的 EU 参考实验室，以便确认器械对 CS 或制造商所选定其他解决方案的符合性，以确保保持一定的安全等级和至少等同的性能。

EU 参考实验室应在 60 天内提出科学性意见。

4.12. 为验证所生产的 D 类器械是否符合要求，制造商应对所生产的各批器械进行试验。得出对照和试验结论后，制造商应立即将这些试验的相关报告转寄给公告机构。此外，制造商应根据事先商定的条件和详细的协议向公告机构递交所生产各批适用器械的样品，其中应包括：公告机构或制造商应向根据第 100 条所指定的 EU 参考实验室寄送所生产各批器械的样品，以进行相应的试验。EU 参考实验室应将其调查结果通知给公告机构。

4.13. 公告机构在收到样品后，在协商的时间期限内，最多不超过 30 天，没任何其他决定（包括所颁发证书的任何有效条件），制造商即可销售器械。

5. 特定类型器械技术文件评估

5.1. 自测以及床旁检测 B、C 或 D 类器械的技术文件评估

(a) 用于自测以及床旁检测的 B、C 和 D 类器械制造商应向第 3.1 节所述的公告机构申请进行技术文件评估。

(b) 申请表应使公告机构能够了解器械特性和性能的设计，并应使公告机构能够评估器械是否符合本法规的相关设计要求。其应包含：

(i) 检测报告，包括针对预期使用者所进行研究的结果；

(ii) 器械样品（如可行）；必要时，完成技术文件评估后应返还器械；

(iii) 表明器械适用于自测用器械以及患者床旁检测用器械的预期用途的数

据；

(iv) 器械标签和使用说明书中所列出的信息。

公告机构可能要求提供进行的后续试验或通过提供进一步证据所填写的申请表，用于评估符合本法规的要求。

(c) 公告机构应验证器械对本法规附录 I 所述相关要求的符合性。

(d) 公告机构应聘请具有相关理论基础知识及工作经验的人员对申请表进行评估，并为制造商提供技术文件评估报告。

(e) 若器械符合本法规的相关规定，则公告机构应颁发 EC 技术文件评估证书。证书应包含评估结论、有效性条件、批准器械标识所需的数据，若适用，还应包含器械预期用途的说明。

(f) 若此类变更会对已批准器械的安全、性能或预期使用条件产生影响，则这些变更应需要获得颁发 EC 技术文件评估证书的公告机构的批准。若制造商计划进行任何上述变更，则其应通知本文件所述颁发 EC 技术文件评估证书的公告机构。公告机构应评估计划的变更并确定是否需要根据第 48 条对计划的变更重新进行符合性评估，或是否可通过 EC 技术文件评估证书的附录予以说明。对于后者的情况，公告机构应评估变更，并将其决定告知制造商，且若这些变更获得批准，则公告机构还应为制造商提供 EC 技术文件评估证书的附录。

5.2. 伴随诊断技术文件评估

(a) 伴随诊断制造商应向公告机构递交技术文件评估申请表。公告机构应按照本附录第 4.1 至 4.8 节规定程序对该申请进行评估。

(b) 申请表应使公告机构能够了解器械的特性和性能，并应使公告机构能够评估器械是否符合本法规的设计 -相关要求，尤其是与相关医疗器械的适用性。

(c) 在颁发适用于伴随诊断且基于安全与性能概述草案以及使用说明书草案的 EC 技术文件评估证书前，公告机构应根据 2001/83/EC 号指令咨询成员国指定的其中一家主管机构的科学性意见，（或 EMA 或根据本节所述的医疗器械咨询主管机构，根据本点就相关医药有关的器械适用性咨询的医疗器械咨询主管机构）。若医疗器械完全属于欧洲议会和理事会第 726/2004 号（ EU）法规（ [1]）附录的适用范围内，则公告机构应征求 EMA 的意见。若医疗器械已获得授权，或已提交了授权申请，则公告机构应咨询医疗器械咨询主管机构或负责授权工作的 EMA 。

(d) 医疗器械咨询主管机构应在收到所有必要文件的 60 天内给出意见。该 60 天期限可根据合理的依据延长一次，且延长期为 60 天。与器械相关的公告机构文件中应包括意见以及任何可能的更新信息。

(e) 公告机构在做出决定时应适当考虑（ d）所述的特殊意见。公告机构应向）医疗器械咨询主管机构通报其最终决定。应根据第 5.1 节（e）颁发 EC 技术文件评估证书。

（[1]） 2004 年 3 月 31 日欧洲议会和理事会第 726/2004 号欧洲议会（ EC）第 726/2004 号条例，其中规定了批准和监督人用和兽用药用产品的欧共体流程，并建立了欧洲药品管理局 （OJ L 136,30.4, 2004，p.1）。

(f) 若所进行的变更会影响与相关医疗产品相关的器械性能和 /或预期用途和 /或适用性，则在进行这些变更前， 制造商应将这些变更通知给公告机构。 公告机构应评估计划的变更并确定是否需要根据第 48 条对变更的器械重新进行符合性评估，或是否可通过 EC 技术文件评估证书的附录予以说明。 对于后者的情况，公告机构应对变更进行评估，并咨询医疗器械主管机构或前述咨询所涉及的 EMA 。医疗器械咨询主管机构应在收到关于这些变更的所有必要文件的 30 天内给出意见。应根据第 5.1 节（ e）颁发 EC 技术文件评估证书的附录。

第 III 章

行政管理规定

6. 在最后一个器械上市至少 10 年内， 制造商或其授权代表 （若制造商在成员国尚无注册营业场所） ，按照主管机构指示，保管以下文件：

- 欧盟符合性声明；
- 第 2.1 节第五段所述的文件，尤其是第 2.2 节第 2 项（c）点所述流程所产生的数据和记录；
- 第 2.4 节所述变更如的信息。
- 第 4.2 节和第 5.1 节（ b）点所述的文件；以及
- 本附录所述的公告机构决定和报告。

7. 各成员国要求， 若制造商或其在职权范围内所确定的授权代表本节所示期限到期前破产或停止其业务活动，则第 6 节所述文件应在该期限内由主管机构处置。

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附录 X

基于型式检验的符合性评估

1. EU 型式检查是公告机构确定和证明器械（包括其技术文件和相关生命周期过程以及所涵盖的相应代表性器械样品）满足本法规相关规定要求的程序。

2. 申请表

制造商应向公告机构提出评估申请。申请表应当包括：

- 制造商名称和注册地址以及，若由授权代表提出申请表，应提供授权代表名称和注册地址；

- 技术文件请参照附录 II 和附录 III 所述。申请人应提供相关代表性器械样品（“型式”）。必要时，公告机构可要求申请人提供其他样品；

- 对于自测或床旁检测用的器械，申请人应提供检测报告，包括针对预期使用者所进行研究的结果，以及表明器械适用于自测用器械以及患者床旁检测用器械的相关预期用途数据；

- 器械样品（若可行）；必要时，完成技术文件评估后应返还器械；

- 表明器械适用于自测用器械以及床旁检测用器械的相关预期用途数据；

- 器械标签和使用说明书中所列出的信息，

- 未向任何其他公告机构提交同一型式申请表的书面声明，或先前由另一公告机构驳回或在其他公告机构进行最终评估前或其授权代表撤回的任何同一型式申请表的相关信息。

3. 评估

公告机构应：

(a) 检验应由具有技术评价、相关器械评价以及临床证据评价方面的知识和经验人员来进行。公告机构可要求提供根据进行的进一步试验或要求其他证据所填写的申请文件，以使评估符合本法规的相关要求。公告机构应进行与器械相关的适当物理或实验室试验，或要求制造商进行此类试验。

(b) 审查和评估技术文件是否符合本法规中适用于器械的要求，并验证所生产的型式是否符合文件的要求；还应记录所设计的项目是否符合第 8 条或适用的 CS 所述标准的适用规范要求，以及尚未设计的记录项目是否基于第 8 条所述相关标准或相关 CS 标准；

(c) 根据附录 XIII 第 1.3.2 节，评审制造商所递交性能评价报告中的临床证据。就该评审而言，公告机构应聘任临床专业知识丰富的器械审查员。出于该审查之目的，如有必要，聘任在器械临床应用方面具有当前直接经验的专家。

(d) 若临床证据全部或部分基于所公布器械的数据，且这些器械与所评估的器械类似或相同，应评估适用此类数据的适用性，并考虑新趋势和创新等因素。公告机构应明确记录其对于所公布数据等效性、相关性和充分性的结论，以证明数据符合要求。

(e) 根据附录 IX 第 4.8 节，在性能评估的评定报告中明确记录其评估结果。

(f) 进行或安排相应的评估以及必要的物理或实验室试验，以验证在未采用第 8 条或 CS 所述标准的情况下，制造商所采用的解决方案是否满足本法规的通用安全与性能要求；若器械与其他器械相连接， 以便按照预期进行运行， 则应证明在其与具有制造商所规定特性的任何此类器械相连接时，其符合通用安全与性能要求；

(g) 进行或安排相应的评估以及必要的物理或实验室试验， 以验证制造商所选择采用的相关协调标准是否得到了实际采用；

(h) 与申请人商定进行必要评估和试验的场所；以及

(i) 根据第 (a)进行评估和试验，并起草关于其结果的 EC 型式检查报告；

(j) 对于 D 类器械，要求根据第 100 条所指定的参考实验室验证制造商所公布的性能，如适用，还应要求其验证器械对 CS 或制造商所选定其他解决方案的符合性，以确保保持安全等级以及至少同等的性能。验证应包括 EU 参考实验室根据第 48(5) 条所进行的实验室试验。

此外，对于本法规 48（6）条所述的情况，公告机构应按照第 48（6）条所规定的关于制造商性能评估报告的程序咨询 2017 法规 (EU) 第 106 条所述的相关专家。

EU 参考实验室应在 60 天内给出科学性意见。

公告机构的相关器械文件中应包括 EU 参考实验室的科学性意见， 且若适用第 48（6）条所规定的程序，还应包括所咨询专家的看法。公告机构在做出决定时应适当考虑

EU 参考实验室科学性意见，如适用，还应适当考虑根据第 48（6）条所咨询专家提出的看法。若 EU 参考实验室给出的科学性意见表示反对， 则公告机构不得颁发证书。

(k) 对于伴随诊断，根据安全与性能概述草案以及使用说明书草案，向成员国根据第 2001/83/EC 号指令所指定的其中一家主管机构或 EMA （根据本点称为医疗器械咨询主管机构） 咨询其对于与相关医疗器械适用性的意见。 若医疗产品仅在欧洲委员会第 726/2004 号法规附录的适用范围内，则公告机构应咨询 EMA 。若医疗产品获得了许可，或许可申请已提交，则公告机构应咨询医疗器械主管机构或负责许可工作的 EMA 。医疗器械咨询主管机构应在收到所有必要文件的 60 天内提出意见。该 60 天期限可根据合理的依据延长一次，且延长期为 60 天。与器械相关的公告机构文件中应包括医疗器械咨询主管机构的意见以及任何可能的更新信息。 公告机构在做出决定时应适当考虑相关医疗器械咨询主管机构所提出的意见。 其应向相关医疗器械咨询主管机构通报其最终决定；以及

(l) 起草关于第 (a)点中评估和进行的试验结果以及科学性意见的 EC 型式检查报告，包括 C 或 D 类器械或第 2 节第三段所涵盖的性能评估报告。

4. 证书

若型式符合本法规的规定，则公告机构应颁发 EC 型式检查证书。证书应包含制造商的名称和地址、型式检查评估结论、证书有效性条件以及批准型式标识所需的数据。

应根据附录 XII 起草证书。文件的相关部分应附于证书之后，且公告机构应保存其副本。

5. 型式变更

5.1. 申请人应将涉及批准型式或其预期用途和使用条件的任何变更计划通知颁发 EC 型式检查证书的公告机构。

5.2. 若批准器械（包括其预期用途和使用条件的限制）的变更会影响通用安全与性能要求或产品使用条件，则这些变更应需要颁发 EC 型式检查证书的公告机构的进一步批准。公告机构应审查计划的变更，将其决定告知制造商，并为其提供 EC 型式检查报告的增补附录。对批准型式任何变更的批准应作为 EC 型式检查证书的增补附录附于其后。

5.3. 批准器械预期用途和使用条件（预期用途和使用条件的限制除外）的变更必需重新申请进行符合性评估。

5.4. 若这些变更会影响器械制造商声称的性能或对 CS 的符合性或制造商所选定且 EC 型式检查证书所批准的其他解决方案，则公告机构应咨询前述咨询所涉及的参考实验室，以便确认器械对 CS 或制造商所选定其他解决方案的符合性，以确保保持安全等级以及至少同等的性能。

EU 参考实验室应在 60 天内给出科学性意见。

5.5 若这些变更会影响 EC 型式检查证书所批准伴随诊断的性能或预期用途或与医疗产品相关的适用性，则公告机构应咨询前述咨询所涉及的医疗器械主管机构或 EMA 。医疗器械咨询主管机构应在收到关于这些变更的有效文件后 30 天内提出意见（若有） 。对批准型式任何变更的批准应作为 EC 型式检查证书的附录附于其后。

6. 行政管理规定

在最后一个器械上市至少 10 年内，制造商或其授权代表（若制造商在成员国尚无注册营业场所），按照主管机构指示，保管以下文件：

- 第 2 节第二段所述的文件；
- 第 5 节所述变更的信息，
- EC 型式检查证书副本、科学性意见与报告及其附录 /增补附录。

附录 IX 第 7 节应适用。

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附录 XI

基于生产质量保证的符合性评估

1. 制造商应确保实施批准的医疗器械生产质量管理体系，按照第 3 节的规定进行最终检验，并接受第 4 节所述的监管。

2. 在制造商应履行第 1 节所规定的义务时，保存根据第 17 条和附录 IV 起草的符合性评估流程所涵盖器械的 EC 符合性声明。 制造商可通过发布 EC 符合性声明来确保并声明相关器械满足本法规中适用规定的要求，且若对 C 类和 D 类器械进行了型式检验，则还可确保并声明相关器械符合 EC 型式检查证书所述型式的要求。

3. 质量管理体系

3.1. 制造商应向公告机构提出申请，评估自己的质量管理体系。

申请应当包括：

- 附录 IX 第 2.1 节所列的所有要素；
- 附录 II 和 III 所述批准型式的技术文件；
- 附录 X 第 4 节所述 EC 型式检验证书副本；若提出申请后，EC 型式检验证书由同一公告机构颁发，则提供的技术文件及其更新信息和所颁发证书的参考资料应包含在申请中。

3.2. 质量管理体系的实施应确保各个阶段对 EC 型式检查证书所述型式以及本法规中适用于器械规定的符合性。质量项目、质量计划、质量记录等质量手册和书面政策和流程中应系统且有序地记录制造商质量管理体系中所采用的所有要素、要求和规定。

文件尤其应包括对附录 IX 第 2.2 节（a)、（b)、（d）和（ e）点所列所有要素的适当说明。

3.3. 附录 IX 第 2.3 节第 1 和 2 项的规定适用。

若质量管理体系可确保器械符合 EC 型式检查证书所述型式的要求，且该体系符合本法规的相关规定，则公告机构应颁发 EC 生产质量保证证书。 公告机构应通知制造商其颁发证书的决定，该决定应包含公告机构审核和合理评估的结论。

3.4. 附录 IX 第 2.4 节的规定适用。

4. 监管

附录 IX 第 3.1 节、第 3.节第一段、第二段和第四段、第第 3.6 和 3.7 节的规定适用。

5. 所生产 **D** 类器械的验证

5.1. 对于 D 类器械，制造商应对所生产的各批器械进行试验。得出质控和试验结论后，制造商应立即将这些试验的相关报告转寄给公告机构。此外，制造商应根据事先商定的条件和详细协议向公告机构递交所生产各批适用器械的或批次，其中应包括：

公告机构或制造商应向根据第 100 条所指定的 EU 参考实验室寄送所生产器械的或批次，以进行相应的实验室试验。参考实验室应将其试验结果通知给公告机构。

5.2. 除非公告机构在收到、任何其他决定（尤其包括所颁发证书的任何有效性条件）后的商定时间期限（但不超过 30 天）内与制造商进行了沟通，否则制造商可将器械上市。

6. 行政管理规定

在最后一个器械上市至少 10 年内，制造商或其授权代表（若制造商在成员国尚无注册营业场所），按照主管机构指示，保管以下文件：

- EC 符合性声明；
- 附录 IX 第 2.1 节第五段所述的文件；
- 附录 IX 第 2.1 节第八段所述的文件，包括附录 X 所述的 EC 型式检查证书；
- 附录 IX 第 2.4 节所述变更的信息；以及
- 附录 IX 第 2.3、3.3 和 3.4 节所述的公告机构决定和报告。

附录 IX 第 7 节应适用。

附录 XII

由公告机构签发的证书

第 I 章

一般要求

1. 应用欧盟的其中一种官方语言起草证书。

2. 各证书均应仅参考一种符合性评估流程。

3. 证书应仅颁发给一家制造商。 证书中的制造商名称和地址应与第 27 条所述电子系统中所注册的名称和地址相同。

4. 证书适用范围的内容应明确说明所涵盖的器械。

   (a) EC 技术文件评估证书和 EC 型式检查证书应包括器械的明确标识，包括器械的名称、 型号和型式、 制造商使用说明书所示且经过符合性评估流程评估的预期用途）、风险分类以及第 24（b）条所述的基本 UDI - DI 。

   (b) EC 质量管理体系证书和 EU 生产质量保证证书应包括器械标识或器械组别、风险分类和预期用途。

5. 公告机构应能够按要求说明证书涵盖哪些（单一）器械。公告机构应能够建立一个确定证书所涵盖器械（包括其分类）的体系。

6. 如适用，证书应包含本证书或根据本法规规定颁发的其他证书所涵盖的器械上市的相关备注。

7. A 类无菌器械的 EC 质量管理体系证书和 EU 生产质量保证证书应包括一份由公告机构审核的声明，以规限生产质量管理体系中与生产相关的安全和无菌条件。

8. 在增补、修改或重新颁发证书时，新证书其应包含先前证书的参考资料及其颁发日期以及变更标识。

第 II 章

证书的必需内容

1. 公告机构名称、地址和标识号；

2. 制造商和授权代表（如适用）的名称和地址；

3. 证书的唯一标识号；

4. 符合第 28（2）条要求的制造商单一注册号；

5. 发布日期；

6. 失效日期；

7. 符合本附录第 I 部分第 4 节规定的器械明确标识所需数据（如适用） ；

8. 符合第 I 章第 8 节规定的先前证书参考资料（如适用）；

9. 符合所进行符合性评估要求的本法规和相关附录参考资料；

10 所进行的检验和试验，例如相关 CS、协调标准、检验报告 /审核报告的参考资料；

11. 涵盖器械上市所需技术文件相关部分或其他证书的参考资料（如适用）；

12 公告机构的监管信息（如适用）；

13. 公告机构针对相关附录的符合性评估结论；

14 证书有效性的条件或限制；

15. 符合相关国家法律要求且具有法律约束力的公告机构签名。

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- 不同发展阶段的概要，包括确定科学有效性、分析性和临床性能的序列和方法（包括里程碑指示和潜在验收标准说明）；

- 本附录第 B 部分所述的 PMPF 计划。

若由于具体的器械特性，性能评估计划认为任何上述要素不适用，则应在计划中提供正当理由。

1.2. 科学有效性、分析性和临床性能证明：一般情况下，制造商应：

- 通过系统的科学文献综述，识别与器械及其预期目的相关的可用数据，并识别数据中任何未解决的问题或缺口；

- 通过评估器械的安全性和性能来确定所有相关数据；

- 生成解决未决问题必需的任何新的或附加的数据。

1.2.1. 科学有效性证明

制造商应基于以下来源之一或组合证明其科学有效性：

- 关于测量相同分析物或标记物的器械的科学有效性的相关信息；

- 科学（同行评审）文献；

- 来自相关专业协会的共识专家意见/立场；

- 概念研究证明结果；

- 临床性能研究结果。

应在科学有效性报告中证明并记录分析物或标记物的科学有效性。

1.2.2. 分析性能证明

除非有任何遗漏可证明不适用，否则制造商应根据附录 I 第 9.1 节（a）点中所述的所有有关参数证明器械的分析性能。

作为一般规则，分析性能应始终在分析性能研究的基础上证明。

对于新型标记物，或其他标记物，在无可用的已认证参考材料或参考测量流程情况下，可能无法证明其真实性。若没有比较方法，若证明其适当，则可使用不同的方法（例如，与其他一些记载详细的方法、或与复合参考标准比较）。在没有这种方法的情况下，需要进行新型器械与当前临床标准实践进行比较的临床性能研究。

应在分析性能报告中证明并记录分析性能。

1.2.3 临床性能证明

除非有任何遗漏可证明不适用，否则制造商应根据附录 I 第 9.1 节（b）点中所述的所有参数证明器械的相关临床性能。

器械的临床性能证明应基于以下来源之一或其组合：

- 临床性能研究；
- 科学同行评审文献；
- 通过常规诊断测试获得的已发表经验。

除非有充分理由根据其他来源的临床性能数据，否则应进行临床性能研究。

应在临床性能报告中证明并记录临床性能。

1.3. 临床证据和性能评估报告

1.3.1 制造商应评估所有相关的科学有效性、分析性和临床性能数据，以验证其器械是否符合附录 I 中所述的通用安全与性能要求。无论其器械能否实现预期的临床有效性和安全性，当按照制造商的说明使用器械时，应允许制造商对该数据的数量和质量进行符合性评估。从该评估中得出的数据和结论应构成器械的临床证据。临床证据应当科学地证明，在目前的医学技术发展最新水平下，预期临床有效性和安全性可实现。

1.3.2 性能评估报告

应在性能评估报告中记录临床证据。本报告应包括科学有效性报告、分析性能报告、临床性能报告和对这些报告的评估，以便证明临床证据。

性能评估报告应特别包括：

- 收集临床证据所采用的方法的理由；
- 文献检索方法和文献检索方案以及文献检索报告；
- 该器械的技术基础、该器械的预期目的以及关于该器械性能或安全性的任何权利要求；
- 所评估的科学有效性以及分析性和临床性能数据的性质和程度；
- 针对医学发展最新水平药物的可接受性能的临床数据；
- 根据本附录 B 部分的 PMPF 报告得出的任何新结论。

1.3.3 对于与根据本附录 B 部分（作为第 10(9) 条所述的性能评估和上市后监管体系的一部分）的制造商 PMPF 计划的执行所得数据相关的器械，应在该器械的整个生命周期内更新性能评估报告中的临床证据及其评估。性能评估报告应为技术文件的一部分。在性能评估中考虑的有利和不利数据也应包含在技术文件。

2. 临床性能研究

2.1. 临床性能研究的目的

临床性能研究的目的在于建立或确定不能通过分析性能研究、 文献和 /或通过常规诊断测试获得的以往经验来确定的器械性能。该信息用于证明符合临床性能方面相关的通用安全与性能要求。当进行临床性能研究时，所获得的数据应用于性能评估流程，并作为器械临床证据的一部分。

2.2. 临床性能研究的伦理考量

临床性能研究各步骤（从首次考虑研究的需要和理由到公布结果）均应根据公认的伦理原则进行。

2.3. 临床性能研究方法

2.3.1. 临床性能研究设计类型

临床性能研究应设计为使数据的相关性最大化，同时使潜在偏差最小化。

2.3.2. 临床性能研究计划

应基于临床性能研究计划（ CPSP）进行临床性能研究。

临床性能研究计划（ CPSP）应定义为临床性能研究的理论、目标、设计和方案分析、方法、监督、执行和记录保存。其应特别包含以下所述信息 (a)如第 66(1)条所述的临床性能研究的单个识别号。

(a) 第 66（1）条所指的临床表现研究的单一识别号；

(b) 申办方标识 —— 包括姓名、注册地址和申办方联系方式，如适用，则其姓名、注册地址及其联系人 /法定代表人联系方式应根据欧盟第 58(4)条确定。

(c) 研究者信息（即协调研究者或其他研究者；资格；联系方式）和研究地点（编号、资格、联系方式） ，对于自测器械，其位置和涉及的非专业人数。

(d) 临床性能研究的开始日期和计划持续时间。

(e) 器械的识别和说明，其预期目的、分析物或标记物、计量溯源性和制造商。

(f) 关于被研究样本类型的信息。

(g) 临床性能研究的总体概况，其设计类型（例如观察性、干预性）以及研究的目的和假设，参考诊断和 /或医学技术发展最新水平中的当前状态。

(h) 在临床实践中技术发展最新水平的背景下，对器械和临床性能研究的预期风险和收益以及除使用剩余样本的研究外，涉及的医疗流程和患者管理的说明。

(i) 器械或试验方案的使用说明、使用者的必要培训和经验、适当的校准流程和质量控制、包括或不包括的任何其他器械、医疗器械、医疗产品或其他物品的指示以及用作参考的任何比较物或比较方法规范，

(j) 说明和证明临床性能研究的设计、其科学稳健性和有效性，包括统计设计以及为尽量减小偏差（例如随机化）和潜在混杂因素管理而采取的措施的细节。

(k) 根据附录 I 第 I 章第 9(1)节(a)点的分析性能有任何遗漏的理由。

(l) 根据附录 I 第 9(1)节(b)要求确定的临床性能参数，以及关于任何遗漏的理由；除了使用剩余样本的研究，一起使用指定的临床结果/终点（主要/次要）和证明，以及对个人健康和/或公共卫生管理决定的潜在影响；

(m) 关于性能研究人群的信息：受试者规范、选择标准、性能研究人群的规模、目标人群的代表性以及（如适用）涉及的弱势受试者（例如儿童、孕妇、免疫力低下或老年人）的信息；

(n) (关于使用剩余样本库、遗传或组织库、患者或疾病登记册等数据的信息，并说明可靠性和代表性以及统计分析方法；保证确定患者样本真实临床状态的相关方法。

(o) 监察计划；

(p) 数据管理；

(q) 决策算法；

(r) 关于任何 CPSP 修订（包括根据第 71 条的修订）或偏离 CPSP 的政策以及明确禁止使用 CPSP 的豁免。

(s) 关于器械的责任，特别是对器械可使用权的控制、关于在临床性能研究中使用的器械的跟踪以及未使用的，过期的或故障器械的返回。

(t) 遵守公认且涉及人类医学研究的伦理原则以及临床性能研究领域的良好临床实践原则以及适用的法规要求的声明。

(u) 知情同意过程的说明，包括患者信息表和知情同意书的副本。

(v) 安全记录和报告流程，包括可记录和可报告事件的定义以及报告流程和时间表。

(w) 暂停或提前终止临床性能研究的标准和流程。

(x) 在完成性能研究后对受试者进行跟踪的标准和流程，在暂停或提前终止的情况下对受试者进行跟踪的流程，撤回知情同意书的受试者和无法跟踪的受试者的跟踪流程。

(y) 在研究之外传达测试结果的流程，包括将测试结果传达给性能研究受试者。

(z) 关于根据第 I 章第 1 节所述的法律要求和伦理原则，建立临床性能研究报告和公布结果的政策。

(aa) 器械的技术和功能特征列表表明其已包含性能研究。

(ab) 参考书目。

若第二段所述的部分资料在单独文件中提交，则应在 CPSP 中所述。对于使用剩余样本的研究，（u）、（x）、（y）和（ z）点均不适用。

若由于所选择的特定研究设计（例如，使用剩余样本与干预性临床性能研究），而使得任何在第二段中所述的要素认为不适合纳入 CPSP，则应提供正当理由。

2.3.3. 临床性能研究报告

由医生或任何其他授权负责人签署的“临床性能研究报告”应包含关于临床性能研究方案计划、临床性能研究结果和结论（包括不利结果）的信息。结果和结论均应透明，没有偏见且和临床相关。报告应包含足够的信息，使独立个体在无需参考其他文件的情况下就可理解。报告还应酌情包括任何方案修订案或偏差，以及具有适当理由的数据剔除。

3. 其他性能研究

通过类比，第 2.3.2 节中所述的性能研究计划和第 2.3.3 节中所述的性能研究报告应记录为其他性能研究而不是临床性能研究。

第 **B** 部分

上市后性能跟踪

4. PMPF 应理解为用于更新本附录第 56 条和第 A 部分所述性能评估的持续过程，并应在制造商上市后监管计划具体说明。为此，在进行 PMPF 时，制造商应主动收集并评估从使用带有 CE 标识、已投放市场或在相关符合性评估流程中所述的预期目的下投入使用的器械中获得的性能和相关科学数据，其目的旨在确认在器械整个预期使用期间的安全性、性能和科学有效性、收益/风险比的持续可接受性以及检测基于事实证据出现的风险。

5. 应根据 PMPF 计划中规定的方法执行 PMPF。

5.1. PMPF 计划应具体说明主动收集和评估安全性、性能和科学数据的方法和流程，目的在于

(a) 确认器械在其预期使用寿命内的安全性和性能，

(b) 标识以前对性能和禁忌症未知的风险或局限性，

(c) 在事实证据的基础上标识并分析突发风险，

(d) 确保附录 I 第 I 章第 1 节和第 8 节所述的临床证据和收益/风险比的持续可接受性，以及

(e) 标识可能的系统误用。

5.2. PMPF 计划应至少包括：

(a) 应用 PMPF 的一般方法和流程，如收集获得的临床经验、使用者反馈、科学文献筛选和其他性能或科学数据来源；

(b) 应用 PMPF 的具体方法和流程（例如，环形比对试验和其他质量保证活动、流行病学研究、合适的患者评估或疾病登记、遗传数据库或上市后临床性能研究）；

(c) （a）和（ b）中所述的方法和流程适当性的理由；

(d) 参考本附录 A 部分第 1.3 节所所述的性能评估报告的相关部分以及附录 I 第 3 节所述的风险管理；

(e) PMPF 要解决的具体目标；

(f) 与等效或类似器械相关的性能数据评估，以及技术发展最新水平；

(g) 参考制造商使用的所有 CS、协调标准和相关 PMPF 指南；

(h) 由制造商进行的 PMPF 活动的详细且充分合理的时间表（例如，PMPF 数据和报告分析）。

6. 制造商应分析 PMPF 结果，并在 PMPF 评估报告中记录结果，该报告应更新性能评估报告并作为技术文件的一部分。

7. 本附录第 56 条和 A 部分所述的性能评估以及附录 I 第 3 节所述的风险管理应考虑 PMPF 评估报告的结论。若通过 PMPF，已经确定预防和/或纠正措施需要，则制造商应执行。

8. 若认为 PMPF 不适合于特定器械，则应在性能评估报告中提供并记录证明。

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附录 XIV

干预性临床性能研究及其他性能研究

第 I 章

干预性临床性能研究和涉及受试者风险的其他性能研究申请表的有关文件

对于用于干预性临床性能研究或涉及受试者风险的其他性能研究的器械，申办方应根据第 58 条提交随附以下文件的申请：

1. 申请表

应及时填写申请表，并包含以下信息：

1.1. 根据欧盟确定的第 58(4)条，申办方的姓名、地址和联系方式以及如适用，联系人或法定代表人姓名、地址和联系方式。

1.2. 若与第 1.1 节不同，用于性能评估的器械的制造商及其授权代表（如适用）的姓名、地址和联系方式。

1.3. 性能研究标题

1.4. 根据第 66(1)条的单一标识号。

1.5. 性能研究状态（例如第一次提交、重新提交、重大修订）；

1.6. 性能研究计划的下昂西信息和参考（例如，包括性能研究的设计阶段细节）。

1.7. 若重新提交已提交的器械申请，则先前提交的日期和参考编号，或在重大修改的情况下，应参考原始申请。申办方应确定上次申请的所有变更以及该等变更的理由，特别是，是否对以前的主管机构或伦理委员会审查结论进行了任何更改。

1.8. 若根据第 536/2014 号（EU）法规，与临床试验申请一并提交本申请，请引用临床试验的正式注册编号。

1.9. 在申请时，确定进行临床性能研究的成员国和第三国应作为多中心或多国研究的一部分。

1.10. 器械性能研究的简要说明，用于提供器械和器械类型必需的分类和其他信息。

1.11. 性能研究计划概要。

1.12. 若适用，关于比对器械的信息，用于提供比对器械必需的分类信息和其他信息。

1.13. 来自申办方的证据表明，临床研究者和研究机构能够根据性能研究计划进行临床性能研究。

1.14. 预期开始日期和性能研究持续时间的细节。

1.15. 将详细信息告知在性能研究申请的所有阶段的公告机构。

1.16. 确认申办方知悉主管机构可与正在进行评估或已评估申请的伦理委员会联系。

1.17. 说明如第 4.1 节所述。

2. 研究者手册

研究者手册（ IB）应包括并在申请时提供的与研究相关的器械性能研究的信息。对新出版的 IB 或其他相关信息的任何更新，应及时提请研究者注意。应明确标识 IB，并特别是应包含以下信息：

2.1. 器械的标识和说明，包括关于预期用途的信息、根据附录 VIII 的风险分类和适用的分类规则、器械的设计和生产以及对前一代器械和类似器械的引用。

2.2. 制造商的安装、保养、保养卫生标准和使用说明（包括储存和处理要求），以及在提供此信息时使用的标签和说明。在器械上市时，应与器械一并提供贴在标签的信息和使用说明。此外，需要任何必需培训的信息。

2.3. 分析性能。

2.4. 现有临床数据，特别是：

- 与器械和/或等效或类似器械的安全性、性能、临床益处、设计特征、科学有效性、临床性能和预期用途有关的相关同行评审科学文献和相关专业协会的共识专家意见或立场；
- 与类似器械的安全性、科学有效性、临床性能、对患者的临床益处、设计特征和预期用途相关的其他相关临床数据，包括相关器械的相似性和差异的详细信息。

2.5. 收益风险分析和风险管理概述，包括已知或可预见的风险和警戒的信息。

2.6. 若器械包含人体、动物或微生物的组织、细胞和物质，其详细信息需遵守与组织、细胞和物质有关的通用安全与性能要求。

2.7. 详细说明附录 I 所列通用安全与性能要求的列表，包括全部或部分适用的标准和 CS，以及满足相关通用安全与性能要求的解决方案说明（只要不符合或仅部分符合该等标准和 CS，或缺失）。

2.8. 在性能研究过程中使用的临床流程和诊断测试的详细说明，特别是关于任何偏离正常临床实践的信息。

3. 性能研究计划 请参见附录 XIII 第 2 和第 3 节。

4. 其他信息

4.1. 由负责生产性能研究器械的自然人或法人签署的声明，除了附录 I 所述的临床性能研究涵盖的方面外，所述器械符合通用安全与性能要求，并且对于该方面，已采取一切预防措施以保护受试者的健康和安全。

4.2. 若国家法律要求，伦理委员会应提供相关的意见副本。根据国家法律，在提交申请时，无需提供伦理委员会意见，但应尽快提交伦理委员会意见副本。

4.3. 根据第 65 条和相应的国家法规，对受伤受试者的保险范围或保险赔偿证明。

4.4. 用于获得知情同意书的文件，包括患者信息表和知情同意文件。

4.5. 说明遵守关于个人资料保护和保密适用规则的安排，特别是：

- 实施组织和技术安排，避免未经授权地访问、披露、传播、变更或丢失已处理的信息和个人数据；
- 说明为确保受试者的记录和个人资料的机密性而采取的措施；
- 说明在数据安全漏洞的情况下将采取的措施，以减轻可能的不利影响。

4.6. 所有可用技术文件的详细资料，例如详细的风险分析 /管理文件或具体的测试报告，应根据要求提交给审查申请的主管机构。

第 II 章

申办方的其他义务

1. 申办方应承诺为国家主管机构保留本附录第 I 章所述的文件提供证据所需的任何文件。若申办方不是负责生产用于性能研究的器械的自然人或法人，则该人可代表申办方履行本义务。

2. 申办方应签署一项协议，以确保研究者及时向申办方报告所有严重不良事件或第 76(2) 所述的其他事件。

3. 本附录中所述的文件应在对有关器械进行临床性能研究结束后至少保存 10 年，或者最后一个器械上市至少 10 年内。

   若申办方或其在职权范围内所确定的联系人在第一子段所示期限到期前破产或停止其活动，各成员国应要求将本附录所述文件保存在主管机构管辖范围内。

4. 申办方应指定一个独立于研究机构的监察员，以确保临床性能研究按照临床性能研究计划、医疗器械临床试验质量管理规范和本法规进行。

5. 申办方应完成对研究受试者的后续工作。

附录 **XV**

对比表

第 **98/79/EC** 号指令	本法规
第 1(1)条	第 1(1)条
第 1(2)条	第 2 条
第 1(3)条	第 2 条第(54)和(55)点
第 1(4)条	-
第 1(5)条	第 5（4）和（ 5）条
第 1(6)条	第 1(9)条
第 1(7)条	第 1(5)条
第 2 条	第 5(1)条
第 3 条	第 5(2)条
第 4(1)条	第 21 条
第 4(2)条	第 19 (1)和（2）条
第 4(3)条	第 19(3)条
第 4(4)条	第 10(10)条
第 4(5)条	第 18(6)条
第 5(1)条	第 8(1)条
第 5(2)条	-
第 5(3)条	第 9 条
第 6 条	-
第 7 条	第 107 条
第 8 条	第 89 和 92 条
第 9（1）条第 1 子段	第 48（10）条第 1 子段
第 9(1)条第二子段	第 48(3)条第二子段，第 48(7)条第二子段和第 48(9)条第二子段
第 9(2)条	第 48(3)至(6)条
第 9(3)条	第 48(3)至(9)条
第 9(4)条	第 5(6)条
第 9(5)条	-
第 9(6)条	第 11(3)至(4)条
第 9(7)条	第 10(7)条
第 9(8)条	第 49(1)条
第 9(9)条	第 49(4)条
第 9(10)条	第 51(2)条

第 **98/79/EC** 号指令	本法规
第 9(11)条	第 48(12)条
第 9(12)条	第 54(1)条
第 9(13)条	第 48(2)条
第 10(1)至(2)条，第 10(3)第二子段和第 10(4)条	第 26（3）条和第 27 条和第 28 条
第 10(3)条第 1 段	第 11（1）
第 11(1)条	第 82（1）和 84（2）条
第 11(2)条	第 82（10）条和第 82（11）条第一子段
第 11(3)条	第 84(7)条
第 11(4)条	-
第 11(5)条	-第 86 条
第 12 条	第 30 条
第 13 条	第 93 条
第 14(1)(a)条	-
第 14(1)(b)条	第 47(3)和(6)条
第 14(2)条	-
第 14(3)条	-
第 15(1)条	第 38 条和第 39 条
第 15(2)条	第 32 条
第 15(3)条	第 40(2)和(4)条
第 15(4)条	-
第 15(5)条	第 51(5)条
第 15(6)条	第 51(4)条
第 15(7)条	第 32(2)和第 40(2)条
第 16 条	第 18 条
第 17 条	第 89 至 92 条
第 18 条	第 94 条
第 19 条	第 102 条
第 20 条	第 97 条
第 21 条	-
第 22 条	-
第 23 条	-
第 24 条	-

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