COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993

concerning medical devices

1993年6月14日理事会第93/42/EEC号关于医疗器械的指令

Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007

经2007年9月5日欧洲议会和委员会2007/47/EC指令修订

目　录

THE COUNCIL OF THE EUROPEAN COMMUNITIES,	欧洲共同体理事会，
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,	依据欧洲经济共同体所制订的罗马条约，特别是第 100a 条规定，
Having regard to the proposal from the Commission	依据执委会的建议案，
In cooperation with the European Parliament	配合欧洲议会，
Having regard to the opinion of the Economic and Social Committee,	依据经济暨社会委员会的意见，
Whereas measures should be adopted in the context of the internal market; whereas the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;	鉴于在内部市场的背景下应采取一些措施；鉴于内部市场是一个无内部疆界的区域，可以保证该区域内的货品、人员、服务及资金的自由流通；
Whereas the content and scope of the laws, regulations and administrative provisions in force in the Member States with regard to the safety, health protection and performance characteristics of medical devices are different; whereas the certification and inspection procedures for such devices differ from one Member State to another; whereas such disparities constitute barriers to trade within the Community;	鉴于各会员国间现存有关医疗器材的安全、对健康的保护及使用特性方面的法律、法规及行政命令的内容及范围不尽相同；鉴于各成员国对这些器械的认证及检验程序也不相同；鉴于前述分歧将阻碍共同体内的贸易活动；
Whereas the national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonized in order to guarantee the free movement of such devices within the internal market;	鉴于医疗器械的使用对患者、使用者、甚至其他人安全及健康保护的相关国家规定应加以协调，以保证此类器械在内部市场能自由流通；
Whereas the harmonized provisions must be distinguished from the measures adopted by the Member States to manage the funding of public health and sickness insurance schemes relating directly or indirectly to such devices; whereas, therefore, the provisions do not affect the ability of the Member States to implement the above mentioned measures provided Community law is complied with;	鉴于协调规定必然与各成员国采取的部分措施有所不同，这些措施是为了管理直接或间接与医疗器械有关的公共健康基金和疾病保险方案；鉴于如果共同体法规与上述措施一致，则这些规定不会影响成员国落实上述措施的能力；
Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of this Directive;	鉴于医疗器械应该为患者、使用者及第三者提供高度的保护，且应该达到制造商所要求的性能水准；鉴于本指令的目的之一是维持或改进各成员国的保护水平；
Whereas certain medical devices are intended to administer medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or	鉴于某些医疗器械预期用于控制药品，该行为符合 1965 年 1 月 26 日委员会指令 65/65/EEC 中的含义。65/65/EEC 指

administrative action relating to proprietary medicinal products; whereas, in such cases, the placing on the market of the medical device as a general rule is governed by the present Directive and the placing on the market of the medicinal product is governed by Directive 65/65/EEC; whereas if, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product shall be governed by Directive 65/65/EEC; whereas a distinction must be drawn between the abovementioned devices and medical devices incorporating, *inter alia*, substances which, if used separately, may be considered to be a medicinal substance within the meaning of Directive 65/65/EEC; whereas in such cases, if the substances incorporated in the medical devices are liable to act upon the body with action ancillary to that of the device, the placing of the devices on the market is governed by this Directive; whereas, in this context, the safety, quality and usefulness of the substances must be verified by analogy with the appropriate methods specified in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products;	令是起源于有关专卖药品的法律、法规或管理规范的规定；鉴于医疗器械的上市基本上由本指令规范，但药品的上市则受 65/65/EEC 号指令规范；鉴于如果某种器械须与其他药品组成一个完整的产品而上市销售、使用，且无法二次使用时，则该组合产品应受 65/65/EEC 号指令规范；鉴于上面提到的医疗器械与包含其他物质的医疗器械应加以区别，该物质单独使用时符合 65/65/EEC 号指令规定的药物；鉴于前述包含于医疗器械的物质若对人体产生作用以辅助医疗器械的作用时，则该医疗器械的上市应由本指令规范；鉴于 1975 年 5 月 20 日 75/318/EEC 号委员会指令（各成员国在测试专卖药品时，有关分析药物毒性和临床标准及方案的法律协调），物质的安全，品质及效用在前述情况下则须依该指令规定的适当方法加以证实；
Whereas the essential requirements and other requirements set out in the Annexes to this Directive, including any reference to 'minimizing' or 'reducing' risk must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety;	鉴于本指令附件所规定的基本要求和其他要求，包括所提及的"最低"或"降低"风险部分的应用，应考虑设计当时的科技水平及实施情形，并在符合高度保护健康和安全的原则下考虑技术及经济的因素；
Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization, rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discretion to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;	鉴于为符合 1985 年 5 月 7 日理事会决议中有关技术协调与标准化新方针所订定的原则，有关医疗器械的设计及制造应遵守相关条款以符合基本要求；鉴于，因为这是基本要求，应该代替相关的国家规定；鉴于这些基本要求在应用时应该谨慎考虑设计当时的科技及实施情形，并在符合高度保护健康和安全的原则下考虑技术及经济的因素；
Whereas Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices is the first case of application of the new approach to the field of medical devices; whereas in the interest of uniform Community rules applicable to all medical devices, this Directive	鉴于 1990 年 6 月 20 日通过的 90/385/EEC 号（各成员国有关有源植入式医疗器械法律调和）理事会指令是第一个应用在医疗器械方面的新方法指令；鉴于为使共同体规定

is based largely on the provisions of Directive 90/385/EEC; whereas for the same reasons Directive 90/385/EEC must be amended to insert the general provisions laid down in this Directive;	适用于所有的医疗器械，本指令基本上是以 90/385/EEC 号指令的条款为依据；鉴于上述的原因，90/385/EEC 号指令也必须增加本指令所列的一般条款的部分；
Whereas the electromagnetic compatibility aspects form an integral part of the safety of medical devices; whereas this Directive should contain specific rules on this subject with regard to Council Directive 89/336/ EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility;	鉴于医疗器械的电磁兼容性是整个产品安全的一部分；鉴于本指令因此须包括 1989 年 5 月 3 日 89/336/EEC 号（各成员国有关电磁兼容性法律调和）理事会指令中所制订的特别规定；
Whereas this Directive should include requirements regarding the design and manufacture of devices emitting ionizing radiation; whereas this Directive does not affect the authorization required by Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation, nor application of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment; whereas Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and the specific directives on the same subject should continue to apply;	鉴于本指令应包含释放电离辐射医疗器械设计及制造的相关要求；鉴于本指令不影响 1980 年 7 月 15 日 80/836/Euratom 理事会指令所需要的授权，该指令旨在修订为保护公众及工作人员健康，防止电离辐射危险而制订基本安全标准的其他指令；本指令亦不影响 1984 年 9 月 3 日 84/466/Euratom 号（制订保护人员在医疗检查或治疗中不受辐射影响的基本方法）理事会指令的应用；鉴于 1989 年 6 月 12 日 89/391/EEC 号理事会指令（鼓励改善工作场所中工作人员的安全与健康）及其他相关主题的指令应持续适用；
Whereas, in order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices; whereas such harmonized European standards are drawn up by private law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on cooperation between the Commission and these two bodies signed on 13 November 1984;	鉴于为证明符合基本要求并使该符合性得以落实，有必要建立协调的欧洲标准，以避免医疗器械在设计、 制造及包装上可能带来的危险；鉴于协调的欧洲标准由私人立法机构制订，而且应维持自愿性质； 鉴于欧洲标准化委员会(CEN) 及欧洲电工标准化委员会(CENELEC) ，依据执委会和这两个团体于 1984 年 11 月 13 日签订的通用协作指南，被认为是有能力制订协调标准的团体；
Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted, on a mandate from the Commission, by either or both of these bodies in	鉴于为了达到本指令的目的，协调标准是前述机构接获理事会任命后，依理事会 1983 年 3 月 28 日通过的

accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, and pursuant to the abovementioned general guidelines; whereas with regard to possible amendment of the harmonized standards, the Commission should be assisted by the Committee set up pursuant to Directive 83/189/EEC; whereas the measures to be taken must be defined in line with procedure I, as laid down in Council Decision 87/373/EEC; whereas, for specific fields, what already exists in the form of European *Pharmacopoeia* monographs should be incorporated within the framework of this Directive; whereas, therefore, several European *Pharmacopoeia* monographs may be considered equal to the abovementioned harmonized standards;	83/189/EEC 号指令（有关技术标准及法规相关资讯提供的程序）而采纳的技术规范（欧洲标准或协调文件），符合前述通用指南的规定；鉴于协调标准的修订有赖于 83/189/EE 号指令建立的委员会的协助；鉴于应采取的措施须依据理事会 87/378/EEC 号指令程序 I 的规定；鉴于特殊领域中现存的欧洲药典专题论文应纳入本指令的架构中；因此数篇欧洲药典专题论文将与前述协调标准有着同等的效力；
Whereas, in Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, the Council has laid down harmonized conformity assessment procedures; whereas the application of these modules to medical devices enables the responsibility of manufacturers and notified bodies to be determined during conformity assessment procedures on the basis of the type of devices concerned; whereas the details added to these modules are justified by the nature of the verification required for medical devices;	鉴于理事会在 1990 年 12 月 13 日通过的 90/683/EEC 号决议（有关技术协调指令适用的符合性评定程序各阶段模式）中制定协调的符合性评定程序；鉴于这些模式在医疗器械的应用，可以依相关器械的型号决定制造商及公告机构在符合性评定程序中应负的责任；鉴于医疗器械所必须的确认有必要在这些模式里增加细节的规定；
Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes; whereas the classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices; whereas the conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products; whereas, for Class IIa devices, the intervention of a notified body should be compulsory at the production stage; whereas, for devices falling within Classes IIb and III which constitute a high risk potential, inspection by a notified body is required with regard to the design and manufacture of the devices; whereas Class III is set aside for the most critical devices for which explicit prior authorization with regard to conformity is required for them to be placed on the market;	鉴于为达到符合性评价的目的有必要将医疗器械分为四类；鉴于分类是以考虑器械的技术设计及制造对易受伤害的人体可能带来的潜在风险为原则；鉴于第 I 类医疗器械对人体可能产生的伤害较轻微，其符合性评定程序通常可完全负由制造商责执行；鉴于对第 II(a)类医疗器械而言，在生产阶段时公告机构的介入应属强制性质；鉴于属于第 II(b)类及第 III 类的医疗器械对人体具有较高的潜在风险，因此在器械的设计及制造阶段必须有公告机构的检验；鉴于第 III 类器械是风险性最高的器械，其符合性需在上市之前获得明确认可；
Whereas in cases where the conformity of the devices can be assessed under the responsibility of the manufacturer the competent authorities must be able, particularly in emergencies, to contact a person responsible for placing the	鉴于器材的符合性如能由制造商负责评鉴，相关主管当局，特别是紧急状况时，应能联络到一位设于共同体内负责将

device on the market and established in the Community, whether the manufacturer or another person established in the Community and designated by the manufacturer for the purpose;	器材在市场上销售的人员，该人员可以是制造商本人或其他设于共同体内经制造商授权的人员；
Whereas medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of this Directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose;	鉴于医疗器材应附加 CE 标志，表示其符合本指令的条款，而得以在共同体市场上自由流通并依其预期目的使用；
Whereas, in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level, medical devices used for protection against the HIV virus must afford a high level of protection; whereas the design and manufacture of such products should be verified by a notified body;	鉴于为抵抗爱滋病，并依据理事会于 1989 年 5 月 16 日采纳有关共同体层次未来防止暨控制爱滋病相关活动的结论，用于防止 HIV 病毒感染的医疗器械应提供高度的人体保护；此类产品的设计及制造应由公告机构证实；
Whereas the classification rules generally enable medical devices to be appropriately classified; whereas, in view of the diverse nature of the devices and technological progress in this field, steps must be taken to include amongst the implementing powers conferred on the Commission the decisions to be taken with regard to the proper classification or reclassification of the devices or, where appropriate, the adjustment of the classification rules themselves; whereas since these issues are closely connected with the protection of health, it is appropriate that these decisions should come under procedure IIIa, as provided for in Directive 87/373/EEC;	鉴于前述的分类规则一般可以将医疗器械适当地分类；鉴于医疗器械性质及相关领域技术进步的性质各不相同，因此必须采取一些措施以决定赋予执委会的执行权力及有关器械的正确分类或再分类，或者于适当时调整分类的规则；鉴于上述的问题与人员健康的保护有着密切的关联，因此这些决议应符合 87/373/EEC 号指令程序 IIIa 规定；
Whereas the confirmation of complicance with the essential requirements may mean that clinical investigations have to be carried out under the responsibility of the manufacturer; whereas, for the purpose of carrying out the clinical investigations, appropriate means have to be specified for the protection of public health and public order;	鉴于制造商有责任执行临床调查以证明其医疗器械符合安全要求；因此为保证大众健康及秩序应明确执行临床调查的适当方法；
Whereas the protection of health and the associated controls may be made more effective by means of medical device vigilance systems which are integrated at Community level;	鉴于最有效的保护健康及相关控制方法是在共同体层次上建立一个医疗器械警戒系统；
Whereas this Directive covers the medical devices referred to in Council Directive 76/764/EEC of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers; whereas the abovementioned Directive must therefore be repealed; whereas for the same reasons Council Directive 84/539/ EEC on 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine must be amended,	鉴于理事会于 1976 年 7 月 27 日通过 76/764/EEC 号指令（有关各会员国最高读数水银玻璃温度计协调法律）中所提及的医疗器械也受本指令规范；前述指令因此必须撤销；基于同样原因，理事会 1984 年 9 月 17 日通过的 84/539/EEC 号指令（有关各会员国人类或动物医疗使用的电动医疗器械法律协调）必须得到修订，

HAS ADOPTED THIS DIRECTIVE:	特采纳本指令：
Article 1 **Definitions, scope**	**第1条** **定义，范围**
1. This Directive shall apply to medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices.	1．本指令适用于医疗器械及其附件。附件在本指令的适用范围内也可视其为医疗器械，以下将两者皆称器械。
2. For the purposes of this Directive, the following definitions shall apply:	2．下列定义适用于本指令的目地：
(a) _M5 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: _	（a）“医疗器械”是指制造商预定用于人体以下目的的任何仪器、装置、器具、软件、材料或其他物品，包括制造商预期特定用于诊断和/或治疗目的和使器械正常应用的软件，无论它们是单独使用还是组合使用：
— diagnosis, prevention, monitoring, treatment or alleviation of disease,	—疾病的诊断、预防、监视、治疗或减轻
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,	—损伤或残障的诊断、监视、治疗、减轻或修补
— investigation, replacement or modification of the anatomy or of a physiological process,	—解剖学和生理过程的探查，替换或变更
— control of conception,	—妊娠的控制
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;	医疗器械不是通过药理学、免疫学或代谢作用等方式在人体内或人体上达到其预定的主要作用，但这些方式有助于其功能的实现。
(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;	（b）“附件”本身虽然不是器械，但由其制造商专门指定与器械一起使用，使其能按照器械制造商预定的器械用途来使用的物品。
(c) '*in vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:	（c）“体外诊断医疗器械”是指制造商预定用于人体，对样本包括来源于人体的血液和组织成分进行体外检测的试剂、试剂产品、校准物、参照物质、试剂盒、仪器、装置、设备或系统，无论它们是单独使用还是组合使用，其目的是为了获取如下方面的信息：
— concerning a physiological or pathological state, or	—关于生理或病理状态，或
— concerning a congenital abnormality, or	

— to determine the safety and compatibility with potential recipients, or — to monitor therapeutic measures. Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination. Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination; (d) 'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The abovementioned prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user _M5 shall not be _ considered to be custommade devices; (e) 'device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Section 2.1 of Annex X in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner; (f) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This	—关于先天性异常，或 —确定与潜在受体的安全性和相容性，或 —对治疗措施进行监视。 样本容器被认为是体外诊断医疗器械。“样本容器”是指制造商预定主要用于盛放和储存来源于人体的用于体外诊断检测样本的器械，该器械可以是真空的，也可以是非真空的。考虑到它们的特性，常规实验室使用的物品不属于体外诊断医疗器械，除非这些产品的制造商设计它们专用于体外诊断检测。 （d）“定制的器械”是指依照执业医疗人员描述的特性而专门制作的器械，该器械是为特定病患设计且专供该患者使用。 前述的器械可以由获得从事该行业的专业资格授权的其他人员提供。 那些为满足医疗人员或其他专业使用人员要求而改装且大量生产的器械不应被认为是订制的器械。 （e）“临床调查用的器械”是指由适当的执业医疗人员在适当的人类临床环境中，执行附录X第2.1所述的调查时所使用的任何器械。 为了开展临床调查，其他具专业资格的人员经授权执行此种临床调查，应视同执业医疗人员； （f）“制造商”是指器械以其名称上市前，负责器械的设计、制造、包装及贴附标签的自然人或法人，无论这些设计、制造等过程是否为自然人或法人亲自执行或委托第三者执行。 本指令所规定有关制造商的责任也适用于将一个或一个以

subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;	上现成的产品加以组装、包装、加工、重新处理和/或附加标签而成为器械，指定其用途并准备以其名称命名上市的自然人或法人。对于那些不属于前述制造商定义者，为个别病患的需要拼装或改装已上市销售的器械的情形不适用本段的规定；
(g) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;	（g）"预期用途"是指制造商于标签上、说明书和/或促销宣称中提供的器械使用须遵循的条件及资料；
(h) 'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;	（h）"上市"是指出于大量行销和/或在共同体市场使用的目的，首次以金钱交易或免费赠送方式提供非临床调查用全新或重新处理过的器械的行为；
(i) 'putting into service' means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;	（i）"开始使用"是指某一器械在共同体市场首次可按照预期用途开始被最终用户使用的时期；
(j) 'authorised representative' means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;	（j）"授权代表"指得到制造商的明确任命，代替制造商行使本指令相关的强制性要求，并能够被共同体内的主管当局或机构联系到的共同体内的任何自然人或法人；
(k) 'clinical data' means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from: — clinical investigation(s) of the device concerned; or — clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or — published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;	（k）"临床数据"是指医疗器械的使用过程中产生的安全和或性能相关信息。临床信息来源于： —相关器械的临床调查；或 —临床调查或科学文献中报道的，可以证明所调查的器械的同类器械的其他研究结果；或 —关于所调查器械的，或可以证明所调查的器械的同类器械的，已发表和/或未发表的关于其他临床经验的报告；
(l) 'device subcategory' means a set of devices having common areas of intended use or common technology;	（l）"器械亚类"指具有相同的工艺或相同的预期应用范围的一组器械；
(m) 'generic device group' means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;	（m）"同类器械组"指具有相同或相似预期用途或共通的工艺，使它们能够划分到同一个种类中而不反映其具体特性
(n) 'single use device' means a device intended to be used once only for a single patient.	
3. Where a device is intended to administer a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, that device shall be governed by this Directive, without prejudice to the provisions of Directive	

2001/83/EC with regard to the medicinal product. If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC. The relevant essential requirements of Annex I to this Directive shall apply as far as safety and performance-related device features are concerned. 4. 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 Article 1 of Directive _M5 2001/83/ EC _ and which is liable to act upon the body with action ancillary to that of the device, _M5 that device shall _ be assessed and authorized in accordance with this Directive. 4 a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive _M5 2001/83/EC _ and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a 'human blood derivative', _M5 that device shall _ be assessed and authorised in accordance with this Directive. 5. _M5 This Directive shall not apply to: _ (a) *in vitro* diagnostic devices; (b) active implantable devices covered by Directive 90/385/EEC; (c) medicinal products covered by Directive 2001/83/EC. In deciding whether a product falls under that Directive or this Directive, particular account shall be taken of the principal mode of action of the product; (d) cosmetic products covered by Directive 76/768/EEC; (e) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a; (f) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, with the exception of devices referred to in paragraph 4a; (g) transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is	的一组器械； （n）"一次性使用器械"指预期被一位患者仅使用一次的器械。 3. 对于用来管理2001/83/EC号指令第一条所定义的药品的器械，在不违背2001/83/EC号有关药品指令条款的规定下，该类器械应受本指令规范。 但是，假若某种器械须与其他药品组合成一完整的产品而上市销售使用，且无法二次使用时，该组合产品应受2001/83/EC号指令规范。本指令附录Ⅰ所列有关器械安全及性能方面的相关基本要求仍然适用。 4．如果医疗器械包含某种物质，而该物质单独使用时符合2001/83/EC号指令第一条对药品的定义，且可能对人体产生作用以辅助医疗器械的作用时，该器械应依照本指令的规定加以评定并认可。 4 a. 如果医疗器械包含某种物质，而该物质单独使用时符合2001/83/EC号指令第一条对药品的定义，可以被看作是来源于人类血液或人类血浆的药品组分或药品（此后均称为"人类血液衍生物），且能对人体产生作用以辅助医疗器械的作用时，该器械应依照本指令的规定加以评定并认可。 5．本指令不适用于下列器械： （a）体外诊断器械； （b）受90/385/EEC号指令规范的有源植入式医疗器械； （c）受2001/83/EC指令规范的药品。在判定一个产品是药品还是器械时，应着重考虑产品的主要作用模式； （d）受76/768/EEC号指令规范的化妆品； （e）人源性的血液、血制品、血浆或血细胞，或上市时包

rendered non-viable or non-viable products derived from animal tissue. 6. Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled. 7. This Directive is a specific Directive within the meaning of Article 1(4) of Directive 2004/108/EC of the European Parliament and of the Council. 8. This Directive shall not affect the application of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, nor of Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure.	含这类血制品、血浆或细胞的器械，4a中提到的器械除外； （f）人源性的移植物、组织或细胞，人源性组织或细胞的衍生物，与人源性组织或细胞组合的产品，4a中提到的器械除外； （g）动物源性的移植物、 组织或细胞；但利用无活性的动物组织或其产品而制造的器械则不在此限。 6．如果一个器械被制造商设计为既按照本指令，又按照关于个人防护设备的89/686/EEC号指令规范进行应用，则89/686/EEC号指令中与基础健康和安全有关的要求应该得到满足。 7.本指令是欧洲议会和委员会2004/108/EC号指令第1条第4点的内容所包含的特别指令。 8．本指令不影响 1996 年 5 月 13 日通过的 96/29/Euratom 指令及 1997 年 6 月 30 日通过的 97/43/Euratom 指令的实施。96/29/Euratom 指令设定基本安全标准，来保护工作人员和公众的健康免受离子放射引起的危害；97/43/Euratom 指令保护个人健康免受与医疗照射有关的离子辐射造成的危害。
Article 2 **Placing on the market and putting into service** Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.	**第2条** **上市及使用** 各成员国必须采取所有必要的措施，以确保只有医疗器械在满足本指令的要求，并被适时地提供，正确地安装和维护，且按照它们的预期目的而进行使时，方可投放市场和/或使用。
Article 3 **Essential requirements**	**第3条** **基本要求**

The devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned. Where a relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machineryshall also meet the essential health and safety requirements set out in Annex I to that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I to this Directive.	考虑了器械的预期用途后，该器械必须符合附录Ⅰ所列适用的基本要求。 如果存在相关的危害，符合欧洲议会和委员会2006年5月17日通过的2006/42/EC机械指令第2条a款的器械，应该满足该指令附录Ⅰ中基本健康和安全要求，这些基本健康和安全要求比本指令附录Ⅰ中给出的基本要求更为明确。
Article 4 **Free movement, devices intended for special purposes** 1. Member States shall not create any obstacle to the placing on the market or the putting into service within their territory of devices bearing the CE marking provided for in Article 17 which indicate that they have been the subject of an assessment of their conformity in accordance with the provisions of Article 11. 2. Member States shall not create any obstacle to: — devices intended for clinical investigation being made available to medical practitioners or authorized persons for that purpose if they meet the conditions laid down in Article 15 and in Annex VIII, — custom-made devices being placed on the market and put into service if they meet the conditions laid down in Article 11 in combination with Annex VIII; Class IIa, IIb and III devices shall be accompanied by the statement referred to in Annex VIII, which shall be available to the particular patient identified by name, an acronym or a numerical code. These devices shall not bear the CE marking. 3. At trade fairs, exhibitions, demonstrations, etc. Member States shall not create any obstacle to the showing of devices which do not conform to this Directive, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply. 4. Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use. 5. Where the devices are subject to other Directives concerning other aspects and which also provide for the affixing	**第4条** **自由流通及特殊目的的器械** 1．各成员国在其领土内不得对附加了第17条所述CE标识的器械的上市及使用设立任何障碍，CE 标识代表该器械已依第11条的规定经过符合性评定的程序。 2．对于下列器械成员国不得设置任何障碍： 一符合第15条及附录Ⅷ规定，供医疗从业人员或经授权的人员执行临床调查而制造的器材； 一符合第11条及附录Ⅷ规定上市及使用的定制器械；属于第Ⅱa、Ⅱb及Ⅲ类器械须附有附录Ⅷ所要求的说明资料，该资料应该能被以姓名、首字母缩写或数字标识的特定患者得到。 以上器械不用加附CE标识。 3．对于不符合本指令的器械，但有明显的标识说明该器械在未符合本指令的规定前不可上市销售或使用时，各成员国不得妨碍其于商展中展示。 4．成员国可以要求专业或非专业用途的医疗器械，其依附录Ⅰ第13点规定供用户及患者使用的相关信息必须以该国语言或其他共同体语言书写。 5．如果某器械在其他方面还受到其他指令的规范，且该指

of the CE marking, the latter shall indicate that the devices also fulfil the provisions of the other Directives. However, should one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the devices fulfil the provisions only of those directives applied by the manufacturer. In this case, the particulars of these directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the directives and accompanying such devices.	令同时包含附加CE标识的说明，则其CE标识表示该器械同时符合其他指令的条款。 但是，如果上述指令中有单一或多数指令允许制造商在一段过渡期间内选择适用的安排，则CE标识只表示符合制造商所选择适用的指令。在此情况下，这些指令的细节，正如欧共体公报所示，必须以指令要求的文件、通知或说明书的形式与这些器械同时提供。
Article 5 **Reference to standards** 1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the *Official Journal of the European Communities*; Member States shall publish the references of such national standards. 2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European *Pharmacopoeia* notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the *Official Journal of the European Communities*. 3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2).	**第5条** **引用标准** 1．对于符合相关国家标准的器械，成员国应假定其符合第3条所述的基本要求，该相关国家标准必须是依照协调标准(其参考号码刊登于欧体公报中) 所采纳的，成员国必须公布前述国家标准的参考号码。 2．依据本指令的目的，本指令的协调标准包括欧洲药典的专题论文，特别是在外科缝合及药品和其他使用的物质之间相互作用两个方面，前述专题论文的参考号码刊登于欧共体公报中。 3．各成员国或执委会如认为协调标准不完全符合第3条所述的基本要求时，成员国针对这些标准所采取的措施及本条第一节的公布事宜应依第6条第二款所规定的程序进行。
Article 6 **Committee on Standards and Technical Regulations** 1. The Commission shall be assisted by the Committee set up by Article 5 of Directive _M5 98/34/EC_, hereinafter referred to as 'the Committee'. 2. Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (2) shall apply, having regard to	**第6条** **标准及技术法规委员会** 1．依据98/34/EC号指令第5条所设立的委员会应给予执委会协助，此后均称为"委员会"。 2．如果本条被引用，则指令1999/468/EC的第3条和第7条

the provisions of Article 8 thereof. 3. The Committee shall adopt its rules of procedure.	也适用，由此第8条的规定也必须注意。 3．委员会应该遵循其议事规则。
Article 7 1. The Commission shall be assisted by the Committee set up by Article 6(2) of Directive 90/385/EEC, hereinafter referred to as 'the Committee'. 2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months. 3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. 4. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	**第7条** 1．依据90/385/EEC号指令第6条第二款所设立的委员会应给予执委会协助，此后均称为"委员会"。 2．如果本段被引用，则1999/468/EC指令的第5条和第7条也适用，由此第8条的规定也必须注意。1999/468/EC指令第5条（6）中期限应该被设定为3个月。 3．如果本段被引用，则1999/468/EC指令的第5条（1）到（4）和第7条也适用，由此第8条的规定也必须注意。 4．如果本段被引用，则1999/468/EC指令的第5条（1）、（2）、（4）和（6）以及第7条也适用，由此第8条的规定也必须注意。
Article 8 **Safeguard clause** 1. Where a Member State ascertains that the devices referred to in Article 4 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to: (a) failure to meet the essential requirements referred to in Article 3; (b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied; (c) shortcomings in the standards themselves. 2. The Commission shall enter into consultation with the Parties concerned as soon as possible. Where, after such	**第8条** **安全条款** 1．成员国在确定第4条（1）及（2）第二小点所述之器械在正确安装、维护及依其设计目的使用下会危及患者、使用者或第三者的健康和/或安全时，应采取所有适当的暂时性措施从市场撤出该类器械或禁止、限制该类产品上市或使用。成员国应立即通知执委会所采取的措施，说明理由并务必指出上述不符合本指令要求的情形是由于： （a）未能符合第3条所述的基本要求； （b）在未能正确地应用第5条所引用的标准的情况下就声称应用了这些标准； （c）标准本身的缺失。 2．执委会应尽快与相关团体协商。协商后，执委会若发现：

consultation, the Commission finds that: (a) the measures are justified: (i) it shall immediately so inform the Member State which took the measures and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the Parties concerned, bring the matter before the Committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the advisory procedure referred to in Article 6(2); (ii) when necessary in the interests of public health, appropriate measures designed to amend non-essential elements of this Directive relating to withdrawal from the market of devices referred to in paragraph 1 or to prohibition or restriction of their placement on the market or being put into service or to introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4); (b) the measures are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorised representative. 3. Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof. 4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.	（a）措施被证明是正确的： （i）应立即通知采取该措施的成员国。 第一项情形若是因为标准本身的缺失造成时，执委会应与相关团体展开协商，如果发现成员国有意维持其决定应将此事于协商后的两个月内通知第6条第一项所述的委员会，并启动第6条第二项提及的忠告性程序。 （ii）为了满足公众健康的利益，符合第7条第3项所提到的监管程序，用来修改本指令中关于第1段所提及的器械从市场上的撤出的非基本条款的适宜措施，或者禁止或限制它们投放市场或投入使用，或为此类器械投放市场而制定的具体要求，应该被采纳。在紧急强制情况下，委员会可以使用第7条第四项中提到的应急程序。 （b）成员国所采取的措施不合理，则应立即通知该成员国及制造商或其授权代表。 3. 对于不符合本指令要求而附加CE标识的器械，成员国应对附加标识的人员采取适当的措施并通知执委会及其他成员国。 4. 执委会应确保将本程序的进展及结果及时通知成员国。
Article 9 **Classification** 1. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. 2. In the event of a dispute between the manufacturer and the notified body concerned, resulting from the application of the classification rules, the matter shall be referred for decision to the competent authority to which the notified body is subject.	**第9条** **分类** 1. 器械应分为I类、IIa类、IIb类、III类。分类的方法应依照附录IX的规定执行。 2. 制造商与公告机构之间若因分类原则的应用而发生争议时，全案将由该公告机构所隶属的成员国主管当局裁决。 3. 如果成员国认为附录IX所述的分类原则，依据技术进展

3. Where a Member State considers that the classification rules set out in Annex IX require adaptation in the light of technical progress and any information which becomes available under the information system provided for in Article 10, it may submit a duly substantiated request to the Commission and ask it to take the necessary measures for adaptation of classification rules. The measures designed to amend non-essential elements of this Directive relating to adaptation of classification rules shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).	和任何在第十条所述的信息系统中可用的信息而需要加以修改，成员国应该及时向委员会提交具体的要求，要求委员会采取必要的措施对分类规则进行修订。依据第7条第三项提及的监督程序，用于修改本指令与分类规则的修订有关的非基本条款的措施应该被采纳。
Article 10 **Information on incidents occuring following placing of devices on the market** 1. Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Directive, regarding the incidents mentioned below involving a Class I, IIa, IIb or III device is recorded and evaluated centrally: (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph(a), leading to systematic recall of devices of the same type by the manufacturer. 2. Where a Member State requires medical practitioners or the medical institutions to inform the competent authorities of any incidents referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorized representative _M5_____ _, is also informed of the incident. 3. After carrying out an assessment, if possible together with the manufacturer or his authorised representative, Member States shall, without prejudice to Article 8, immediately inform the Commission and the other Member States of measures that have been taken or are contemplated to minimise the recurrence of the incidents referred to in paragraph 1, including information on the underlying incidents. 4. Any appropriate measures to adopt procedures to implement this Article shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).	**第10条** **器械上市后所发生事故的相关信息** 1．成员国对于符合本指令要求的I、IIa、IIb及III类器械有关下列事故的信息应加以记录并集中评估： （a）器械的特性和/或性能不良或退化的情形，以及可能或已导致患者或使用者死亡或健康状况严重恶化的不充分标识或使用说明； （b）(a)项所描述的与器械的特性和/或性能有关的技术上或医学上的原因，导致制造商有系统回收同型号的器械。 2．成员国要求医疗从业人员或医疗机构向其主管机关提供第一项所述任何事故的资料时，应同时采取必要的措施以确保相关器材的制造商或其设于共同体的授权代表得到该事故的通知。 3．有关第一项所述的事故，成员国在执行评估后(如果可能的话，会同制造商或其授权代表执行评估)，应在不影响第8条的规定的前提下立即通知执委会及其他已采取或准备采取措施降低第一项所述的事故再次发生的几率的成员国，包括潜在事故的相关信息。 4．依据第7条第二项中提到的监管程序，所有用于采纳程序以便执行本条款的适当措施，应被采纳。

Article 11 Conformity assessment procedures	第11条 符合性评估程序
1. In the case of devices falling within Class III, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either: (a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or (b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with: (i) the procedure relating to the EC verification set out in Annex IV; or (ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).	1．对于第III类器械，除定制或临床调查用的器械外，制造商应依下列程序之一附加CE标识： （a）附录II所列有关EC符合声明程序(完全品质保证)；或 （b）附录III所列有关EC型式试验程序，并配合下列二者之一： （i）附录IV所列有关EC证明程序；或 （ii）附录V所列有关EC符合声明程序(制程品质保证)
2. In the case of devices falling within Class IIa, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VII, coupled with either: (a) the procedure relating to the EC verification set out in Annex IV; or (b) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or (c) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance). Instead of applying these procedures, the manufacturer may also follow the procedure referred to in paragraph 3 (a).	2．对于第IIa类器械，除定制或临床调查用的器械外，制造商依附录VII有关EC符合声明程序及下列三种程序之一附加CE标示： （a）附录IV所列有关EC证明程序；或 （b）附录V所列有关EC符合声明程序(制程品质保证)；或 （c）附录VI所列有关EC符合声明程序(产品品质保证)。 除本项所列之程序外，制造商应采取第三项(a) 点的程序。
3. In the case of devices falling within Class IIb, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, either: (a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); in this case, point 4 of Annex II is not applicable; or (b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with: (i) the procedure relating to the EC verification set out in Annex IV; or (ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance); or (iii) the procedure relating to the EC declaration of conformity set out in Annex VI (product quality assurance).	3．对于IIb类器械，除定制或临床调查用的器械外，制造商应依下列程序之一附加CE标识： （a）附录II所列有关EC符合声明程序(完全品质保证)；但附录II第四点在此不适用；或 （b）附录III所列有关EC型试验程序，并配合下列三种程序之一： （i）附录IV所列有关EC证明程序；或 （ii）附录V所列有关EC符合声明程序(制程品质保证)；或 （iii）附录VI所列有关EC符合声明程序(产品品质保证)。
4. The Commission shall, no later than five years from the date of implementation of this Directive, submit a report to the Council on the operation of the provisions referred to in Article 10 (1), Article 15 (1), in particular in respect of	4．执委会应自本指令实施之日起的五年内向理事会提出报

Class I and Class IIa devices, and on the operation of the provisions referred to in Annex II, Section 4.3 second and third subparagraphs and in Annex III, Section 5 second and third subparagraphs to this Directive, accompanied, if necessary, by appropriate proposals.	告，必要时提出建议案；报告中应包括第10条第(1)款，第15条第(1)款中第I、IIa类器械规定及本指令附录II 4.3点第二、三段，附录III第5点第二、三段的实施情形。
5. In the case of devices falling within Class I, other than devices which are custom-made or intended for clinical investigations, the manufacturer shall, in order to affix the CE marking, follow the procedure referred to in Annex VII and draw up the EC declaration of conformity required before placing the device on the market.	5．对于第I类器械，除定制或临床调查用的器械外，制造商在上市前应依据附录VII所列程序出具EC符合性声明，以便附加CE标识。
6. In the case of custom-made devices, the manufacturer shall follow the procedure referred to in Annex VIII and draw up the statement set out in that Annex before placing each device on the market.	6．制造商将特制的器械上市前应依据附录VIII的程序并出具该附录符合性声明。
Member States may require that the manufacturer shall submit to the competent authority a list of such devices which have been put into service in their territory.	成员国可要求制造商向其主管当局提交在该成员国境内上市的器械目录。
7. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture.	7．在器械的符合性评定过程中，制造商和/或公告机构应考虑所有依据本指令已经在生产过程中执行的合理的评估和确认活动的结果。
8. The manufacturer may instruct his authorized representative_M5_____ _ to initiate the procedures provided for in Annexes III, IV, VII and VIII.	8．制造商可通知其授权代表进行附录III、IV、VII和VIII中描述的程序。
9. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative _M5_____ _, may apply to a body of his choice within the framework of the tasks for which the body has been notified.	9．符合性评定程序中若需要公告机构的介入，制造商或其授权代表可以自行从欧共体公布的相关公告机构中选择合适的机构参与其符合性评定的工作。
10. The notified body may require, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.	10．公告机构对制造商所选的符合性评定程序，在合理范围内，可要求制造商提供建立及维持该程序所需的资料或数据。
11. Decisions taken by the notified bodies in accordance with_M5 Annexes II, III, V and VI _ shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, _M5 for further periods of a maximum length of five years _.	11．公告机构依据附录II、III、V和VI所作的决定，有效期最长为五年，制造商申请并由双方签署合约后，有效期限最多可再延长五年。
12. The records and correspondence relating to the procedures referred to in paragraphs 1 to 6 shall be in an official language of the Member State in which the procedures are carried out and/or in another Community language acceptable to the notified body.	12．第一段至第六段所述相关程序的记录及文件往来均应采用其所在成员国的官方语言，和/或公告机构所能接受的

13. By derogation from paragraphs 1 to 6, the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 to 6 have not been carried out and the use of which is in the interest of protection of health.	其共同体语言书写。 13．对于未按照第一至六段程序执行符合性评定，但其目的为保护健康所用的个别器械，主管当局在制造商提出合理的要求下，可允许在成员国境内上市行销并使用。
14. The measures designed to amend non-essential elements of this Directive, by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).	14．依据第7条第（3）款中监管程序的规定，由于技术改进，并考虑的有关器械的预期用途，可开展附录Ⅰ第13.1部分描述的活动。那些通过补充本指令的非基本要求以对其进行修订，并与前述活动有关的措施应被采纳。
Article 12 **_M5 Particular procedure for systems and procedure packs and procedure for sterilisation _**	**第12条** **系统和组装器械及灭菌程序的特殊程序**
1. By way of derogation from Article 11 this Article shall apply to systems and procedure packs.	1．当第11条条文未能落实时，本条适用于系统和组装器械。
2. Any natural or legal person who puts devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that: (a) he has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and (b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and (c) the whole activity is subjected to appropriate methods of internal control and inspection. Where the conditions above are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant procedure pursuant to Article 11.	2．任何自然人或法人将附有CE标识的器械，依其预期目的及制造商限定的使用范围组合在一起，并以系统或组装的器械在市场上销售者，应出具一份声明书，声明： （a）其已证实器械之间的相容性符合制造商的说明，并已依说明作业；及 （b）其已将此系统的或组装的器械加以包装，并综合制造商说明及相关资讯供使用者参考；及 （c）所有的活动均由适当的内部控制及检验方法管理。 在不符合上述条件的情况下，如该系统或组装器械包含了未附加CE标识的器械或器械的组合，或选定的组合与其原先的预期用途不符合时，该系统或组装器械本身应被视为一个器械，如同那些符合第11条的相关程序的器械。
3. Any natural or legal person who sterilises, for the purpose of placing on the market, systems or procedure packs referred to in paragraph 2 or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at his choice, follow one of the procedures referred to in Annex II or V. The application of the	3．自然人或法人为使器械上市，而对第二段所述的系统或组合器械，或制造商要求在使用前进行灭菌的其他附有CE标识的医疗器械实施灭菌工作者，应选择执行附录Ⅱ或附

abovementioned Annexes and the intervention of the notified body are limited to the aspects of the procedure relating to the obtaining of sterility until the sterile package is opened or damaged. The person shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions. 4. The products referred to in paragraphs 2 and 3 themselves shall not bear an additional CE marking. They shall be accompanied by the information referred to in point 13 of Annex I which includes, where appropriate, the information supplied by the manufacturers of the devices which have been put together. _M5 The declarations referred to in paragraphs 2 and 3 shall be kept at the disposal of the competent authorities for a period of five years. _	录Ⅴ所述程序之一。前述程序的应用及公告机构的介入只限于程序的以下方面：无菌包装被打开或损坏之前器械无菌状态的获得。该自然人或法人应出具一份声明，声明灭菌活动已按照制造商的说明开展。 4．第二、三项所述的产品不需附加额外的CE标识，但应附有附录Ⅰ第13点所述的信息，适当时，应包括被组装的单个器械的制造商提供的信息。 第二、三项所述的声明书应在主管当局保存五年。
Article 12a **Reprocessing of medical devices** The Commission shall, no later than 5 September 2010, submit a report to the European Parliament and to the Council on the issue of the reprocessing of medical devices in the Community. In the light of the findings of this report, the Commission shall submit to the European Parliament and to the Council any additional proposal it may deem appropriate in order to ensure a high level of health protection.	**第12a条** **医疗器械的再加工** 委员会应在2010年9月5日前向欧洲议会和理事会关于共同体内医疗器械的再加工事宜提交一份报告。 依据该报告的发现，为了确保高度的健康保护，委员会应向欧洲议会和理事会提交任何其他认为合适的提案。
Article 13 **Decisions with regard to classification and derogation clause** 1. A Member State shall submit a duly substantiated request to the Commission and ask it to take the necessary measures in the following situations: (a) that Member State considers that the application of the classification rules set out in Annex IX requires a decision with regard to the classification of a given device or category of devices; (b) that Member State considers that a given device or family of devices should, by way of derogation from the provisions of Annex IX, be classified in another class; (c) that Member State considers that the conformity of a device or family of devices should, by way of derogation from Article 11, be established by applying solely one of the given procedures chosen from among those referred to in Article 11;	**第13条** **关于分类和排除条款的决议** 在下列情况下，成员国应及时向委员会提交具体的要求，并要求委员会采取必要的措施： （a）成员国认为附录Ⅸ所述的分类原则的应用必须对某个或某类器械的分类作出判定时；或 （b）成员国认为某器械或某系列器械若不能落实附录Ⅸ的规定，应归在其他类时； （c）成员国认为某器械或某系列器械，若不能落实第11条的规定，只能适用第11条所述程序的某一种时； （d）成员国认为需要判定某个器械或某系列器械应属于第1条第（2）款（a）到（e）条的其中之一条时。

(d) that Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2)(a) to (e). The measures referred to in the first subparagraph of this paragraph shall, as appropriate, be adopted in accordance with the procedure referred to in Article 7(2). 2. The Commission shall inform the Member States of the measures taken.	依据第7条第（2）款所述的程序，适当时，应采取本项的第1小项中所述的措施。 2．委员会应向成员国通报所采取的措施。
Article 14 **Registration of persons responsible for placing devices on the market** 1. Any manufacturer who, under his own name, places devices on the market in accordance with the procedures referred to in Article 11 (5) and (6) and any other natural or legal person engaged in the activities referred to in Article 12 shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned. For all medical devices of _M5 classes IIa, IIb and III _, Member States may request to be informed of all data allowing for identification of such devices together with the label and the instructions for use when such devices are put into service within their territory. 2. Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union. For devices referred to in the first subparagraph of paragraph 1, the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of the details referred to in paragraph 1. 3. The Member States shall on request inform the other Member States and the Commission of the details referred to in the first subparagraph of paragraph 1 given by the manufacturer or authorised representative.	**第14条** **负责器械上市行销人员的注册** 1．依第11条第（5）、（6）款所述的程序，将器械以自己的名义上市的制造商，或从事参与第12条所述活动的自然人或法人，应将其注册的公司地址及相关器械的描述通知其所在成员国的主管当局。 对于IIa、IIb和III类的医疗器械，在成员国境内投入使用时，能够对这些器械和标签及使用说明书进行标记的所有数据应向成员国通报。 2．以自己的名义将器械投放市场的制造商，如果在成员国境内没有注册经营场所，则该制造商应在欧盟指定唯一的授权代表。对于第1项第1小项所涉及的器械，授权代表应将第1项中所提及的，他自己的经注册的经营场所的细节信息，通知成员国境内的主管当局。 3．会员国有义务向其他成员国与委员会通报第1项第1小项所述的，由制造商或授权代表提交的细节信息。
Article 14a **European databank** 1. Regulatory data in accordance with this Directive shall be stored in a European database accessible to the competent authorities to enable them to carry out their tasks relating to this Directive on a well informed basis.	**第14a条** **欧洲数据库** 1．本指令所要求的数据应储存在一个主管当局能够进入的欧洲数据库中，以便他们能够在信息充足的基础上完成本

The databank shall contain the following: (a) data relating to registration of manufacturers and authorised representatives and devices in accordance with Article 14 excluding data related to custom-made devices; (b) data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused according to the procedures, as laid down in Annexes II to VII; (c) data obtained in accordance with the vigilance procedure as defined in Article 10; (d) data relating to clinical investigations referred to in Article 15. 2. Data shall be forwarded in a standardised format. 3. The measures necessary for the implementation of paragraphs 1 and 2 of this Article, in particular paragraph 1(d), shall be adopted in accordance with the regulatory procedure referred to in Article 7(2). 4. The provisions of this Article shall be implemented no later than 5 September 2012. The Commission shall, no later than 11 October 2012, evaluate the operational functioning and the added value of the databank. On the basis of this evaluation, the Commission shall, if appropriate, present proposals to the European Parliament and the Council or present draft measures in accordance with paragraph 3.	指令相关的任务。 该数据库应包含以下内容： （a）符合第14条要求，与制造商和授权代表及器械的注册有关的数据。定制器械相关的数据除外。 （b）根据附录II到附录VII所述的程序，对认证证书进行签发、变更、补充、暂停、撤销或拒绝的相关数据； （c）第10条所述的警戒系统所获得的数据； （d）第15条所述的临床调查相关的数据。 2．应该以标准的格式提交数据。 3．为执行本条的第1项和第2项，特定条件下，第1项（d）款应依据第7条第（2）款所述的程序采取必要措施。 4．本条的规定最晚于2012年9月5日起执行。委员会应在2012年10月11日前对数据库的运行功能和增值能力进行评价。基于该评价，适当时委员会应依据第3项的要求，向欧洲议会和理事会提交议案，或提交初步措施。
Article 14b **Particular health monitoring measures** Where a Member State considers, in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. The Member State shall then inform the Commission and all other Member States, giving the reasons for its decision. The Commission shall, whenever possible, consult the interested Parties and the Member States. The Commission shall adopt its opinion, indicating whether the national measures are justified or not. The Commission shall inform all the Member States and the consulted interested Parties thereof.	**第14b条** **健康监督专用措施** 对于特定的某个产品或某组产品，为了确保保护健康和安全，或为了确保遵守公共健康要求，如果某个成员国认为该产品应从市场上撤出，或者应禁止或限制该产品投放市场和投入使用，或依据相关的要求进行管理，则可以采取任何合理的过渡措施。 然后，该成员国应向委员会和其他成员国进行通报，并就其决定给出理由。 可能的话，委员会应同相关方和成员国进行磋商。 委员会应采纳成员国表明国家措施合理与否的主张。委员

When appropriate, the necessary measures designed to amend nonessential elements of this Directive, relating to withdrawal from the market, prohibition of placing on the market and putting into service of a certain product or group of products or to restrictions or introduction of particular requirements in order for such products to be put on the market, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 7(4).	会应向所有成员国及一同磋商的相关方进行通报。 适当时，依据第7条第（3）款所述的程序，应该采纳必要措施对本指令的如下基本要求进行修订：关系到某个产品或某组产品从市场上的撤出，对该产品上市和投入使用的禁止或限制，或制定其他使产品上市的特定要求。在紧急强制情况下，委员会可以采用第7条第（4）款中的应急程序。
Article 15 **Clinical investigation** 1. In the case of devices intended for clinical investigations, the manufacturer or the authorised representative, established in the Community, shall follow the procedure referred to in Annex VIII and notify the competent authorities of the Member States in which the investigations are to be conducted by means of the statement mentioned in Section 2.2 of Annex VIII. 2. In the case of devices falling within Class III and implantable and long-term invasive devices falling within Class IIa or IIb, the manufacturer may commence the relevant clinical investigation at the end of a period of 60 days after notification, unless the competent authorities have notified him within that period of a decision to the contrary based on considerations of public health or public policy. Member States may however authorise manufacturers to commence the relevant clinical investigations before the expiry of the period of 60 days, insofar as the relevant ethics committee has issued a favourable opinion on the programme of investigation in question, including its review of the clinical investigation plan. 3. In the case of devices other than those referred to in paragraph 2, Member States may authorise manufacturers to commence clinical investigations immediately after the date of notification, provided that the ethics committee concerned has issued a favourable opinion on the programme of investigation in question including its review of the clinical investigation plan. 4. The authorization referred to in paragraph 2 second subparagraph and paragraph 3, may be made subject to authorization from the competent authority.	**第15条** **临床调查** 1．对用于临床调查的器械，制造商或其在共同体设立的授权代表应执行附录VIII的程序并通知依据附录VIII2.2所述的声明开展调查工作的成员国的主管当局。 2．对于第III类及有源植入或长期装设于人体的IIa、IIb类器械，除非主管当局基于大众健康及公共政策的考量，于接获前述制造商通知的六十日内作出反对的决定，制造商可在六十日后先行展开临床调查工作。 但是，在相关伦理委员会提出赞成调查方案包括临床调查计划的意见后，会员国应授权制造商在六十日的期限截止前先行展开临床调查工作。 3．对于第二项所述之外的其他器械，在相关伦理委员会提出赞成调查方案包括临床调查计划的意见后，成员国可以授权制造商自通知发出之日起即展开临床调查工作。 4．第二项第二小段及第三项的授权工作可由成员国的主管当局负责。 5．临床调查必须依照附录X的规定进行。依据第7条第（3）款所述的程序，与附录X中的临床调查规定有关，对本指令

5. The clinical investigations must be conducted in accordance with the provisions of Annex X. The measures designed to amend nonessential elements of this Directive, inter alia by supplementing it, relating to the provisions on clinical investigation in Annex X shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3). 6. The Member States shall, if necessary, take the appropriate steps to ensure public health and public policy. Where a clinical investigation is refused or halted by a Member State, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State shall inform the Member States concerned about its actions and the grounds for the actions taken. 7. The manufacturer or his authorised representative shall notify the competent authorities of the Member States concerned of the end of the clinical investigation, with a justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds this notification shall be communicated to all Member States and the Commission. The manufacturer or his authorised representative shall keep the report referred to in Section 2.3.7 of Annex X at the disposal of the competent authorities. 8. The provisions of paragraphs 1 and 2 do not apply where the clinical investigations are conducted using devices which are authorized in accordance with Article 11 to bear the CE marking unless the aim of these investigations is to use the devices for a purpose other than that referred to in the relevant conformity assessment procedure. The relevant provisions of Annex X remain applicable.	的非基本要求进行修订的措施，尤其是通过补充而进行修订的措施应该被采用。 6．成员国应在必要时采取适当的措施以确保大众健康及公共政策。如果某项临床调查被成员国拒绝或中断，该成员国应向其他成员国和委员会通报其决定和做出决定的背景。如果成员国要求对某项临床调查做出显著的修订或临时的中断，该成员国应向相关成员国通报其行为和采取该行为的背景。 7．制造商或其授权代表应在临床调查结束后通知相关成员国的主管当局，如果提前结束，应给出合理的理由。有关安全的临床调查，如果提前结束，应通知所有的成员国及委员会。制造商或其授权代表应保存附录X第2、3、7点所述的报告，以供主管当局查阅。 8．临床调查的目的若与相关符合性评定程序的目的相同，且该项调查所使用的器械是依第 11 条程序授权附加 CE 标识的器械时，该器械不适用于第一项及第二项的规定，但仍适用附录 X 的相关规定。
Article 16 **Notified bodies** 1. The Member States shall notify the Commission and other Member States of the bodies which they have designated for carrying out the tasks pertaining to the procedures referred to in Article 11 and the specific tasks for which the bodies have been designated. The Commission shall assign identification numbers to these bodies, hereinafter referred to as 'notified bodies'. The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities.* It shall	**第16条** **公告机构** 1．成员国应将负责执行第11条所述程序的指定机构名单及工作项目通知执委会及其他会员国。 执委会应给予这些机构各自的识别号码，以下称这些机构为"公告机构"。 执委会应将公告机构的名单、识别码及其工作项目公布于欧体公报上，并确保资料的更新。 2．成员国应按照附录XI所列的标准指定上述的公告机构。

ensure that the list is kept up to date. 2. Member States shall apply the criteria set out in Annex XI for the designation of bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonized standards shall be presumed to meet the relevant criteria. When appropriate in the light of technical progress, the detailed measures necessary to ensure a consistent application of the criteria set out in Annex XI for the designation of bodies by the Member States shall be adopted in accordance with the regulatory procedure referred to in Article 7(2). 3. A Member State that has notified a body shall withdraw that notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof. 4. The notified body and the manufacturer, or his authorized representative _M5_____ _, shall lay down, by common accord, the time limits for completion of the assessment and verification operations referred to in Annexes II to VI. 5. The notified body shall inform its competent authority about all certificates issued, modified, supplemented, suspended, withdrawn or refused and the other notified bodies within the scope of this Directive about certificates suspended, withdrawn or refused and, on request, about certificates issued. The notified body shall also make available, on request, all additional relevant information. 6. Where a notified body finds that pertinent requirements of this Directive have not been met or are no longer met by the manufacturer or where a certificate should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body shall inform its competent authority thereof. The Member State shall inform the other Member States and the Commission. 7. The notified body shall, on request, supply all relevant information and documents including budgetary documents, required to enable the Member State to verify compliance with Annex XI requirements.	国家标准是转订自相关协调标准者，符合国家标准的机构亦视其符合相关的标准。 依据技术进步，适当时，应按照第7条第（2）款所述的程序，采纳细致的必要措施，以确保附录XI中成员国指定公告机构的相关标准持续有效。 3．成员国在发现某机构不再符合第2项的标准时，应撤销该机构的资格，并应立刻通知其他成员国及执委会。 4．公告机构与制造商或其授权代表应在达成共识的前提下，设定完成附录II至附录VI所述的评价及确认作业的时间。 5．公告机构应通知其主管当局关于认证证书签发、更改、补充、暂停、撤销或拒绝的信息，以及本指令范围内其他公告机构关于认证证书签发、更改、补充、暂停、撤销或拒绝的信息。公告机构有义务提供其他相关的信息。 6．如果公告机构发现制造商不能满足或不再满足本指令中的相关要求，或者签发了本不该签发的认证证书，考虑到相称性原则，应暂停或撤销已签发的证书，或对其采取限制措施，直到制造商采取适当的纠正措施以确保相关的要求得到满足。在对证书进行暂停或撤销或其他任何限制措施，或有必要让主管当局接入干预时，公告机构应通知其主管当局。该成员国应通知其他成员国和委员会。 7．必要时，公告机构应提供所有的信息和文件包括预算表，以便成员国能够验证附录XI的要求被满足的情况。

Article 17 **CE marking** 1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market. 2. The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging. It shall be accompanied by the identification number of the notified body responsible for implementation of the procedures set out in Annexes II, IV, V and VI. 3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of theCE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.	**第17条** **CE 标识** 1．除定制或临床调查用的器械外，符合第3条基本要求的器械应于上市时附加CE符合标识。 2．CE符合标识，如附录XII所示，应以明显易见且不易磨损的方式附加于器械本体或包装的适当位置； 如果可行，亦应附加于使用说明书及销售的包装上。 CE符合标识后应有负责执行附录II、IV、V和VI所述程序的公告机构的识别号码。 3.器械上应禁止附加任何在形式及意义上易与CE标识造成混淆而有欺瞒第三者之虞的标志或说明。其余的标志在不影响CE标识的可见度及清晰度的情况下，即可附加于器械上，包装上或附随器械的说明文件上。
Article 18 **Wrongly affixed CE marking** Without prejudice to Article 8: (a) where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the Directive, the manufacturer or his authorised representative shall be obliged to end the infringement under conditions imposed by the Member State; (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure in Article 8. Those provisions shall also apply where the CE marking has been affixed in accordance with the procedures in this Directive, but inappropriately, on products that are not covered by this Directive.	**第18条** **错误附加的CE标识** 在不违背第八条所述的情况下： （a）成员国若发现CE标识以不当的方式附加于产品上，或未按照本指令的要求附加CE标识时，制造商或其授权代表有义务依照成员国要求，立即停止此违规行为； （b）若不符合的情形继续存在，成员国必须按照第8条的程序采取所有适当的措施以限制或禁止该项产品上市，或确保该产品自市场上撤回。 以上规定同样适用于已经按照本指令的程序不恰当地在本指令未涵盖的产品上附加了CE标识的情况。
Article 19 **Decision in respect of refusal or restriction**	**第19条** **关于拒绝或限制的决定**

1. Any decision taken pursuant to this Directive: (a) to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations; or (b) to withdraw devices from the market, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject. 2. In the event of a decision as referred to in paragraph 1, the manufacturer, or his authorized representative _M5_____, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measure to be taken.	1．依照本指令所作的下列决定： （a）拒绝或限制器械的上市或使用，或临床调查工作的开展；或 （b）将器械自市场撤回， 应说明此决定所根据的确切理由。上述决定应尽快通知相关团体，并告知其余相关成员国现行国家法律中可采用的补救措施以及这些补救措施实施的期限。 2．成员国在做出第1项中所述决定前，应给予制造商或其授权代表解释其立场的机会，除非事情过于紧急而无法事先举行咨商。
Article 20 **Confidentiality** 1. Without prejudice to the existing national provisions and practices on medical confidentiality, Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law. 2. The following information shall not be treated as confidential: (a) information on the registration of persons responsible for placing devices on the market in accordance with Article 14; (b) information to users sent out by the manufacturer, authorised representative or distributor in relation to a measure according to Article 10(3); (c) information contained in certificates issued, modified, supplemented, suspended or withdrawn. 3. The measures designed to amend non-essential elements of this Directive, *inter alia* by supplementing it, relating to determination of the conditions under which other information may be made publicly available, and in particular for Class IIb and Class III devices to any obligation for manufacturers to prepare and make available a summary of	**第20条** **保密** 1．在不影响现有的国家规定，以及医疗保密作业的情况下，成员国应确保所有参与本指令施行的团体对其在开展工作过程中取得的所有资料都应保密。 这并不影响成员国及公告机构彼此交换信息及提出警告的义务；亦不影响相关人员依刑法规定提供资讯的义务。 2．下列信息都应被视为机密： （a）依据第14条负责器械上市的注册人员的信息； （b）依据第10条第（3）款，由制造商、授权代表或销售商设定的提供给用户的相关措施的信息； （c）证书签发、更改、补充、暂停或撤销的信息。 3．依据第7条第（3）款的监管程序，应采取如下的措施对本指令的非基本要求通过补充进行修订：判定其他信息可被公开的条件，尤其是对IIa类和III类器械，制造商出于义务而为和器械相关的信息和数据准备的摘要。

the information and data related to the device, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3).	
Article 20a **Cooperation** Member States shall take appropriate measures to ensure that the competent authorities of the Member States cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive. Without prejudice to the provisions of this Directive, cooperation may be part of initiatives developed at an international level.	**第20a条** **协作** 为了本指令的统一执行，成员国应采取适当的措施以确保各成员国的主管当局相互协作，并与委员会协作，相互传递必要的信息。 委员会应该组织负责市场监督的主管当局进行经验交流，以协调本指令的统一执行。 在不违背本指令的情况下，应在国际层面上开展积极的协作。
Article 21 **Repeal and amendment of Directives** 1. Directive 76/764/EEC is hereby repealed with effect from 1 January 1995. 2. In the title and Article 1 of Directive 84/539/EEC, 'human or' is deleted. In Article 2 of Directive 84/539/EEC, the following subparagraph is added to paragraph 1: 'If the appliance is at the same time a medical device within the meaning of Directive 93/42/EEC (*) and if it satisfies the essential requirements laid down therein for that device, the device shall be deemed to be in conformity with the requirements of this Directive. 3. Directive 90/385/EEC is hereby amended as follows: 1. in Article 1 (2) the following two subparagraphs are added: '(h) "placing on the market" means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished; (i) "manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations	**第21条** **指令的修订和废止** 1．76/764/EEC 号指令自1995年1月1日起撤销。 2．84/539/EEC号指令标题及第1条中的"人类或"用语删去。 84/539/EEC号指令第2条第一项增加一小段： "若该器械为同时受93/42/EEC号指令所规范的医疗器械且符合该医疗器械所规定的基本要求，则该器械应视其为符合本指令的要求" 3．90/385/EEC号指令修改如下: 1．第1条第（2）款增加下列两小段： "（h）"上市"是指出于大量行销和/或在共同体市场使用的目的，首次以金钱交易或免费赠送方式提供非临床调查用全新或重新处理过的器械的行为；" "（i）"制造商"是指将器械以其名义上市前负责器械的设计、制造、包装及标识的自然人或法人，无论前述设计、 制造

are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;'	等是否为该自然人或法人亲自执行或委托第三者执行。” 本指令所规定有关制造商的责任也适用于将一个或一个以上的产品加以组装、包装、加工、重新处理和/或附加标识而成为一个器械，指定其用途并准备以其名义上市的自然人或法人。对于那些不属于前一段制造商定义者，为个别病患的需求制作或改装已上市销售的器材的情形不适用本段的规定：
2. in Article 9 the following paragraphs are added: '5. During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture. 6. Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer, or his authorized representative established in the Community, may apply to a body of his choice within the framework of the tasks for which the body has been notified. 7. The notified body may require, where duly justified, any information or data which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure. 8. Decisions taken by the notified bodies in accordance with Annexes II and III shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of five years. 9. By derogation from paragraphs 1 and 2 the competent authorities may authorize, on duly justified request, the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the procedures referred to in paragraphs 1 and 2 have not been carried out and the use of which is in the interest of protection of health.';	2. 第九条增加下列几项: “5. 在器械的符合性评定过程中，制造商和/或公告机构应参与制造阶段按照本指令执行的任何评定及确认活动的结果。 6. 符合性评定程序中如果需要公告机构的介入，制造商或其授权代表可以从欧体公布的相关公告机构中选择一个机构参与其符合性评定的工作。 7. 公告机构对制造商所选的符合性评定程序，应在合理的情况下要求制造商提供建立或维持该程序所需的资料或数据。 8. 公告机构根据附录II和附录III做出的决定， 最长有效期限为五年； 制造商申请并由双方签署合约后， 有效期限可再延长五年。 9. 对于未按照第一项和第二项程序开展符合性评定，但出于保护健康的目的而使用的个别器械， 主管当局在制造商提出合理要求的情况下，可允许其在成员国境内上市行销并使用。
3. the following Article 9a is inserted after Article 9: *'Article 9a* 1. Where a Member State considers that the conformity of a device or family of devices should be established, by	3. 第九条之下增加第9a条: 第9a条

way of derogation from the provisions of Article 9, by applying solely one of the given procedures chosen from among those referred to in Article 9, it shall submit a duly substantiated request to the Commission and ask it to take the necessary measures. These measures shall be adopted in accordance with the procedure referred to in Article 7 (2) of Directive 93/42/EEC (*). 2. The Commission shall inform the Member States of the measures taken and, where appropriate, publish the relevant parts of these measures in the *Official Journal of the European Communities*. 4. Article 10 shall be amended as follows: — the following subparagraph shall be added to paragraph 2: 'Member States may however authorize manufacturers to start the clinical investigations in question before the expiry of the 60- day period, provided that the Ethical Committee concerned has delivered a favourable opinion with respect to the investigation programme in question.', — the following paragraph shall be inserted: '2a. The authorization referred to in the second subparagraph of paragraph 2 may be subject to approval by the competent authority.'; 5. the following is added to Article 14: 'In the event of a decision as referred to in the previous paragraph the manufacturer, or his authorized representative established in the Community, shall have an opportunity to put forward his viewpoint in advance, unless such consultation is not possible because of the urgency of the measures to be taken.'	1．成员国如果认为某器械或某类器械，不符合第9条的规定，只能用第9条所述程序的某一种时，应向执委会提出适当且有根据的要求，并请执委会采取必要的措施。前述措施的采纳应依93/42/EEC号指令第7条第(2)款的程序进行。 2．执委会应将上述采取的措施通知所有成员国，并在适当时在欧体公报中刊登相关部分。 4．第10条修改如下： 一第2项增加下列一小段： “但是在相关伦理委员会提出赞成调查方案的意见后，成员国可授权制造商在六十日的期限截止前先行展开临床调查的工作。” 一插入下列一项： “2a 第2项第2小段的授权工作须经主管当局的同意。” 5．第14条增加下列内容： “成员国在做出上述决定前，应给予制造商或其授权代表解释其立场的机会，除非事情遏于紧急而无法事先举行咨商。”
Article 22 **Implementation, transitional provisions** 1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 July 1994. They shall immediately inform the Commission thereof. The Standing Committee referred to in Article 7 may assume its tasks from the date of notification (1) of this Directive. The Member States may take the measures referred to in Article 16 on notification of this Directive. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be	**第22条** **执行及过渡性条款** 1．各成员国必须于1994年7月1日前采纳并公布符合本指令所需的法律、规章及行政条款，并应立即通知执委会。 第七条所述的常设委员会应自本指令发出通告之日起开始运作，成员国在接获本指令的通告后应采取第16条所述的措施。 成员会采纳前述条款时，应包括本指令的引用资料，或在

adopted by Member States. Member States shall apply these provisions with effect from 1 January 1995. 2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive. 3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 11 (1) to (5) for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices. 4. Member States shall accept: — devices which conform to the rules in force in their territory on 31 December 1994 being placed on the market during a period of five years following the adoption of this Directive, and — the aforementioned devices being put into service until 30 June 2001 at the latest. In the case of devices which have been subjected to EEC pattern approval in accordance with Directive 76/764/EEC, Member States shall accept their being placed on the market and put into service during the period up to 30 June 2004.	公布条款时附上这些引用资料。成员国应采纳这种引用的程序。 成员国制订的相关条款自1995年1月1日起实施。 2．成员国应将本指令涵盖范围内的相关国家法律条款告知执委会。 3．成员国应采取必要措施，以确保负责第11条第1项至第5项符合性评定工作的公告机构能参考任何有关此类器材特性及性能的资料，特别是依照已存在有关此类器械的国家法律、规章或行政条款所执行的相关测试及证明结果。 4．成员国应接受： —采纳本指令的五年内应继续准许符合该国1994年12月31日前施行的规定的医疗器械上市，和 —上述器械至少在2001年6月30日前仍在投入使用。 对于符合 76/764/EEC 号指令且已经过 EC 型式批准的医疗器械，成员国应准许其上市并使用至 2004 年 6 月 30 日。
Article 23 This Directive is addressed to the Member States.	**第23条** 本指令向所有成员国发送。
ANNEX I **ESSENTIAL REQUIREMENTS** **I. GENERAL REQUIREMENTS** 1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will 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 intended 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.	**附录 I** **基本要求** **I. 一般要求** 1．器械的设计和制造应使其在设计的使用条件下使用时，不得危及患者的临床状况或安全，或危及使用者的安全及健康，适当时，亦不应危及其他人的安全及健康，而且在权衡利弊下，使用该器械可能引发的危险应在可接受的范围内，并符合高度保护健康及安全的要求。

This shall include: — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: — eliminate or reduce risks as far as possible (inherently safe design and construction), — where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, — inform users of the residual risks due to any shortcomings of the protection measures adopted. 3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. 4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients 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. 5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. 6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. 6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	这应包括： —尽可能减小由于器械的人体工学特性造成的误用，以及器械预期的使用环境而导致的风险，和 —考虑预期使用者（非专业人员、专业人员、残疾人或其他的使用者）的技术知识、经验、教育和培训，适当时，还要考虑医疗和物理条件。 2．制造商于设计及生产器械时所采用的方法，应符合安全原则，并考虑广泛认可的技术发展水平。 制造商在选择最适当的方法时应依序应用下列原则： —尽可能排除或减轻可能产生的风险(安全设计及生产)， —对于无法排除的风险，应采取适当的保护措施，必要时应给出警告， —通知使用者有关保护措施的缺失而可能导致的剩余风险。 3．器械的功能达到制造商的要求并依其明订的方法设计、制造及包装，以便适合第1条第二款(a)点所述的一项或多项功用。 4．在制造商指定的使用期限内，当器械承受在正常使用条件下出现的压力时，前面三点所述的器械性质及功能，不得对患者的临床状况或安全(或适当时其他人员)产生负面的影响。 5．器械的设计、制造及包装不得使其在依制造商提供的说明资料运送及贮存时使其性质或功能受损。 6．在权衡器械的设计功能时，所附加不良副作用应在可接受的范围内。 6a．依据附录X的要求，若要表明符合基本要求，则必须包

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION	括临床评估资料。 II．有关设计和制造的要求
7. Chemical, physical and biological properties	7．化学、物理和生物学特性
7.1. The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: — the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, — the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device, — where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	7.1．器械的设计及制造应保证符合第I部分"一般要求"所述之性质及性能，并应特别留意下列三点： 一所用材料的选择，特别要注意有毒性，或易燃材料的选择； 一考虑到器械的预期目的，应注意所用的材料与生物组织、细胞和体液之间的相容性， 一适用时，有效性已被预先证实的生物物理学研究或模型研究的结果。
7.2. The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	7.2．基于器械的预期用途，其设计、制造及包装应将运送、贮藏及使用中污染物或残留物对相关人员或患者造成的风险降至最低。另外应特别留意所接触的组织及接触的时间及频率。
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	7.3．器械的设计、制造及包装应确保其在正常使用及例行程序中接触材料、物质及气体时仍能安全使用；如果是控制药品的器械，则依据该药品有关的规定及限制，该器械的设计与制造应与相关药品兼容，并保持其预期用途相关的性能。
7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/ EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical 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 or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (1) on the quality	7.4．与某种物质组合的器械，该物质单独使用时符合2001/83/EC号指令第1条的定义，且可能对人体产生作用以辅助器械的作用时，该物质的安全性、品质及有用性应考虑器械本身的用途，必须依据 对于第一段提到的物质，公告机构应结合器械的预期用途，对该物质作为医疗器械的一部分的有用性予以证实，依据

and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related 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 established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. 7.5. The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on	与物质的质量和安全，包括该物质与器械联合的临床受益/风险权衡有关的第726/2004/EC规则，从成员国指定的主管当局或欧洲药品局，具体通过他的委员会的作用，寻找科学的意见。在给出意见时，主管当局或欧洲药品局应考虑该器械的生产过程，并考虑公告机构确定的，该物质与器械联合后有用性方面的数据。 如果某器械与人类血液衍生物联合并将其作为不可分割的部分，公告机构应结合器械的预期用途，对该物质作为医疗器械的一部分的有用性予以证实，从欧洲药品局，具体通过有关物质的质量和安全包括将人类血液衍生物与器械联合后的受益/风险权衡的委员会的作用，寻找科学的意见。在给出意见时，欧洲药品局应考虑该器械的生产过程，并考虑公告机构确定的，该物质与器械联合后有用性方面的数据。 如果改变与器械联合的辅助性物质，尤其是与生产过程相关的辅助性物质，该改变应通知公告机构，并应同相关的药物主管当局（如，与初步磋商有关的药物主管当局）进行磋商，以确保保持该辅助物质的质量和安全性能。主管当局应考虑经公告机构确定的，该物质与器械联合后有用性方面的数据，以确保这种改变对已经完成的物质与器械联合后的受益/风险权衡不会造成负面影响。 如果相关的药物主管当局（如，与初步磋商有关的药物主管当局）已经获得了有关辅助物质的信息，能够对已完成的关于该物质与器械联合后的受益/风险权衡产生影响，当局应向公告机构提供证据，无论该信息是否对已完成的关于该物质与器械联合后的受益/风险权衡产生影响。公告机

the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1). If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. 7.6. Devices must be designed and manufactured in such a way as to reduce, as much as possible, 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. 8. Infection and microbial contamination 8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use. 8.2. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other_M5 transmissible _ agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	构在重新考虑符合性评价程序的评价时采用先进的科学观念。 7.5．器械的设计和生产应将从器械中泄漏的物质导致的风险降到最低。依据1967年6月27日在与危险物质的分类、包装和标识有关的法律和法规的基础上通过的67/548/EEC指令，对于致癌、致突变或具有生殖毒性的物质应给予特殊的留意。 如果器械的某个部分（或器械自身）预期用于药物、体液或其他物质的管理和/或将以上物质移动到人体或从人体移除，或者预期用于运输和储存该类体液或物质的器械，含有被归入 1 类或 2 类致癌、致突变或具有生殖毒性的物质的邻苯二甲酸盐，依据 67/548/EEC 指令附录 I 的要求，这些器械必须在器械自身和/或独立单元的包装上，适用时包括销售包装上，标明该器械含有邻苯二甲酸盐。 如果这种器械的预期用途涉及到儿童、孕妇或哺乳期妇女，制造商必须在技术文档中、使用说明书中，具体到本段来说，提供使用这些物质对这些患者群体的残留风险的信息满足基本要求的科学解释，可以的话，还应该提供适当的防范措施。 7.6．器械的设计和制造应考虑其用途及其使用环境，以尽可能地降低意外进入器械的物质所造成的风险。 8．传染及细菌污染 8.1．器械及其制造过程必须尽可能减少或降低患者、使用者及第三者受到感染的风险。器械的设计应易于处理并于必要时降低器械在使用中受到患者污染或使患者收到污染的几率。

8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. 8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method. 8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions. 8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer. 8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. 9. Construction and environmental properties 9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use. 9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: — the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, — risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, — the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, — 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.	8.2．动物源性组织应来自受兽医管制及监督的动物，此类管制及监督应按照这些动物组织的预期用途加以调整。公告机构应保有动物产地相关信息。 对于动物源性的组织、细胞及物质应执行加工、保存、测试及处理以便提供最适当的安全程度。特别是有关病毒及其他可传染物质的安全性，应在制造过程中通过施行经确认的去除方法或病毒灭活方法进行证实。 8.3．以无菌状态提供的器械，其设计、制造和一次性使用的包装都应依照适当的程序确保该器械在上市及依规定的条件贮藏或运输时仍保持其无菌的状态，直到保护性包装被破坏或打开为止。 8.4．以无菌状态提供的器械应按照适当有效的方法制造并加以灭菌。 8.5．应行灭菌的器械应在适当控制的条件(如，环境)下制造。 8.6．非无菌器械的包装应使器械保持在指定的清洁程度，若器械在使用前须先行灭菌者，应降低细菌污染的风险；包装的使用应考虑厂商指定的灭菌方法而选择最适当者。 8.7．无菌器械及非无菌器械的相同或相似产品应使用不同的包装和/或标签。 9．结构及环境特性 9.1．器械若与其他器械或设备组合者，该组合体连同其连接系统应顾及安全并不得使其既定功能受损。 任何使用限制应标明于标签上或使用说明书中。 9.2．器械的设计及制造应尽量避免或降低下列风险： —与器械物理特性有关，包括体积/压力比例、大小长宽及

9.3. Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	人类工程学特性，而可能造成伤害的风险， —与可合理预见的环境条件，如磁场、外接电流影响、静电释放、压力、温度或压力及加速度的变化有关的风险， —与正常用于调查或治疗的其他器械相互干扰所造成的危险， —由于器械的材质老化或测量精度或控制机制丧失而无法维护或校正(如植入式器材)所造成的风险。 9.3．器械的设计或制造必须能够使其在正常使用中或出现单一故障时将导致失火或爆炸的风险降至最低。对于使用时须暴露于易燃物质或易引起火灾的物质的器械应特别加以留意。
10. Devices with a measuring function	10．具有测量功能的器械
10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	10.1．具有测量功能的器械的设计及制造，基于其使用目的考量，应在适当的精度范围内提供其足够精确度和稳定性。前述精度范围应由制造商规定。
10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	10.2．基于其目的的考量，器械的测量、监控及显示刻度应在符合人体工程学原理的前提下设计。
10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	10.3．具有测量功能的器械所做的测量结果应以符合80/811/EEC号理事会指令(19)规定的法定单位表示。
11. Protection against radiation	11．辐射保护
11.1. *General*	11.1．通则
11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	11.1.1．器械的设计和制造应在满足预期目的的同时尽量降低患者、使用者及其他人员暴露于辐射的几率，但不得因此而限制治疗及诊断所需的特定辐射水平。
11.2. *Intended radiation*	11.2．预期辐射
11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	11.2.1．器械是设计用于为特定医疗目的而释放足以达到危
11.2.2. Where devices are intended to emit potentially hazardous, visible and/ or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	
11.3. *Unintended radiation*	
11.3.1. 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.	

11.4. *Instructions* 11.4.1. The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation. 11.5. *Ionizing radiation* 11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use. 11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. 11.5.3. Devices emitting ionizing radiation, 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 and energy and where appropriate the quality of radiation. 12. Requirements for medical devices connected to or equipped with an energy source 12.1. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks. 12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. 12.2. Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. 12.3. Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure. 12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate	险程度的辐射量，且患者因此治疗所获得的益处大于辐射造成的危险时，辐射的释放量应可由使用者控制。这种器械的设计和生产应能够确保相关变量范围的可重复性。 11.2.2. 如果器械预期会释放潜在的危害，可见和/或不可见辐射，可行时，应该为该器械加装辐射释放时的视觉显示和/或声音警告。 11.3. 非预期的辐射 11.3.1. 器械的设计和制造应降低患者、使用者及其他人员暴露于非预期的辐射下的几率，如杂散辐射、散射辐射。 11.4. 说明 11.4.1. 释放辐射器械的作业指导书应详细叙述所释放的辐射的性质，对患者及使用者保护的方法，以及避免误用和降低安装风险的方法。 11.5. 离子辐射 11.5.1. 释放电离辐射的器械的设计及制造在可行时应基于器械的目的，确保释出的数量、几何性质及质量可以被改变和控制。 11.5.2. 释放诊断用电离辐射的器械的设计及制造应达到适当的影像和/或输出品质以满足预期医疗目的，且同时须减少患者及使用者暴露在辐射下的机会。 11.5.3. 释放治疗用电离辐射的器械的设计及制造应提供可靠的方法监控释出量，放射线类型及放射线能量，适当时，包括放射线品质。 12. 连接或配有能量源的医疗器械必须符合的要求 12.1. 含有电子可编程系统的器械在设计时应确保这些系统的重复性、可靠性及功能符合预期目的的需要。 系统在出

alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	现单一故障时应采取适当的方法以尽量避免或降低可能造成的风险。
12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	12.1a. 对于整合了软件或本身就是医疗软件的器械，考虑到开发生命周期的原理、风险管理、验证、确认，软件必须依据技术发展水平进行确认。
12.6. *Protection against electrical risks*	12.2. 患者的安全取决于器械内置的电源时，该器械应含有决定供电状态的方式。
Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	12.3. 患者的安全取决于器械外接的电源时，该器械应含有报警系统以对供电不足进行提示。
12.7. *Protection against mechanical and thermal risks*	12.4. 用以监控患者一个或数个临床变量的器械应含有适当的报警系统，以提醒使用者可能导致患者死亡、或使患者健康情形严重恶化的状况。
12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	12.5. 器械的设计和制造应减少在正常环境下使用时产生电磁场而阻碍其他器械或设备运行的风险。
12.7.2. Devices must 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.	12.6. 触电风险保护 器械的设计和制造应尽量使器械在正确安装并正常使用和出现单一故障时避免意外电击事故的风险。
12.7.3. Devices must 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.	12.7. 机械和热相关风险保护 112.7.1. 器械的设计和制造应保护患者及使用者避免遭受机械风险，如抗力、固定及可动零件等相关的风险。
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	12.7.2. 除非震动是器械的预期功能之一，其设计及制造应考虑技术的进步及减轻震动的方法，特别是震动的来源，以便将因器械震动而产生的风险降低到最低水平。
12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	12.7.3. 除非声音的发出是器械的预期功能之一，其设计及制造应考虑技术的进步及降低声音的方法，特别是声音的来源，以便将应因声音而产生的风险降到最低水平。
12.8. *Protection against the risks posed to the patient by energy supplies or substances*	
12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	
12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.	

Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	12.7.4. 使用者需操纵的电气、气体或水压以及气压能源供应终端接头或连接器的设计及连接，应将所有可能的风险降至最低。
12.9. *The function of the controls and indicators must be clearly specified on the devices.*	12.7.5. 器械可接触得到的零件(供热或使温度上升至特定程度用的零件及区域除外)及其四周在正常使用状况下不得达到可能造成潜在危险的温度。
Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	12.8. 能源或能量物质对患者造成的风险的保护
13. Information supplied by the manufacturer	12.8.1. 对于供应患者能量或物质的器械，其设计及架构应使流动速率得以精确地设定和维持，以确保患者和使用者的安全。
13.1. Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.	12.8.2. 器械本身应含有避免和/或表示可能造成危险的不正确流动速率的方式。
This information comprises the details on the label and the data in the instructions for use.	器械应尽可能含有适当的配备以避免能源和/或物质供应源意外地释出能量的危险水平。
As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	12.9. 器械上应清楚地标明其控制及显示功能
Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	器械上含有操作所需的说明或通过可视系统表示操作或调整的参数时，此类信息必须让使用者，适当时和患者了解。
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	13. 制造商提供的信息
13.3. *The label* must bear the following particulars:	13.1. 每台器械基于可能的使用者所接受的训练及知识，应提供所有正确、安全使用所需的信息并应标明制造商。
(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;	这些信息包括标签上的细节及使用说明书中的数据。
(b) the details strictly necessary to identify the device and the contents of the packaging especially for the users;	为使器械能安全地使用，适当并可行时，使用器械所需的信息应标识在器械本体及/或单件包装上，或适当时标识在销售包装上。如无法标识在单件包装上时，应在单个或多个器械所附的说明书上列出。
(c) where appropriate, the word 'STERILE';	
(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	
(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the	除了无需任何说明即可安全使用的I类或IIa类器械外，每台

year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is costum-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by(e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization; (n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative. 13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 13.5. Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. 13.6. Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and(e); (b) the performances referred to in Section 3 and any undesirable sideeffects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the	器械的包装都应包含使用说明。 13.2. 适当时，信息应以符号的形式表示。但任何使用的符号或识别颜色应符合协调标准的规定。不存在相应标准时，该符号及色彩应于器械附加的文件上描述。 13.3. 标签必须包含以下信息： （a）产品名称或商品名以及制造商的地址。进口到共同体的器械，如果制造商在共同体境内没有注册的经营场所，视其在共同体内销售的地区，其标签或外包装或使用说明书上应另外列出授权代表的名称和联系地址。 （b）使用者用以辩识包装内的器械及内容所必需的详细资料； （c）适当时，标明"无菌"字样； （d）适当时，标明批号（置于"LOT"字后）或序列号； （e）适当时，标示器械应使用的期限，为安全起见应以年月表示； （f）适当时，有关器械仅供一次性使用的标示。制造商在共同体境内使用的一次性使用标识必须保持一致。 （g）对于定制器械，应标明"定制器械"字样； （h）对于临床调查用器械，应标明"仅供临床调查用"字样； （i）所有特殊的储存和/或操作条件； （j）所有特殊的操作说明； （k）任何警告事项和/或注意事项； （l）除（e）的使用期限外，有源器械另应有制造年份。本项标示可包含于批号或序列号中； （m）适用时，灭菌方法； （n）如果器械符合第1条第（4a）款的规定，须给出器械

devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I. If the device bears an indication that the device 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. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;	含有人类血液衍生物的标识。 13.4. 器械的预期使用目的对使用者而言若不明显时，制造商应于标签上或说明书中清楚地叙述。 13.5. 合理可行时，器械及其可分离的组件应以适当的批号术语加以标识，以便采取适当的措施寻找该器械及其可分离的组件的潜在风险。 13.6. 适当时，使用说明书中应包含下列资料； （a）第13.3中提到的详细信息，（d）和（e）除外； （b）第3点提到的功能及任何非预期的副作用； （c）如果器械需要和其他医疗器械或设备连接以便依其预期目的进行操作，应包含足够详细的相关特性信息，以便正确的识别所用的器械或设备从而获得安全的组合； （d）用以证明器械正确安装、正常及安全运作所需的资料，及为确保器械持续正常及安全运作所需的维护校正频率及性质等的详细资料； （e）适当时，涉及避免与器械的植入有关的风险的信息； （f）器械用于具体的调查或治疗时，会造成相互干扰的风险的相关信息； （g）无菌包装遭到破损时所需的信息，适当时应包含适宜的重新灭菌方法的详细说明； （h）对于可重复使用的器械，应有容许重复使用的适当过程，包括清洁、消毒、包装以及，适当时，灭菌的方法和重复使用的次数限制。 对于使用前须先行灭菌的器械，其清洁及灭菌的说明应确保在正确执行后仍使器械符合第I节的要求； 如果器械标明为一次性使用，制造商掌所握的，与器械的

(n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function; (q) date of issue or the latest revision of the instructions for use.	再次使用可能导致的风险有关的已知特性和技术因素。如果如13.1所述不需要使用说明书，如果使用者要求，这种信息应该能被得到。 （i）器械使用前需要进一步处理或操作的细节（如灭菌，最后组装等）； （j）医疗用释放辐射的器械，应详细说明其释放的辐射的性质、种类、强度及分布情形。 使用说明应包含医疗人员向患者解释任何禁忌症或注意事项所需的详细资料，特别应包含下列各项： （k）器械性能改变时应注意的事项； （l）在合理可预见的环境条件下，暴露在磁场、外接电气影响、静电释放、压力或压力变化、加速度、燃烧热源等条件应注意的事项； （m）有关器械所控制的药品或产品的适当资料，包含任何所投放的物质的选择限制； （n）有关器械丢弃时应注意的事项，以避免任何由于器械的丢弃而导致的特殊的、不寻常的风险； （o）符合第7.4点规定，与器械结合为整体的医疗物质或人血衍生物； （p）具有测量功能的器械所标称的精确度； （q）使用说明书的签发日期或最新版本。
ANNEX II **EC DECLARATION OF CONFORMITY** **(Full quality assurance system)** 1. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned, as specified in Section 3 and is subject to audit as laid down in Sections 3.3	**附录II** **EC 符合性声明** **（全面质量保证系统）** 1．制造商必须确保使用经批准的产品设计、制造及最终检验质量系统，如第3点所述，并依第3.3点及4点的规定接受

and 4 and to Community surveillance as specified in Section 5.	审核，且依第5点规定接受共同体监督。
2. The EC declaration of conformity is the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned meet the provisions of this Directive which apply to them.	2．EC 符合性声明是一种程序，符合第1点义务的制造商借此程序确保并声明相关产品符合指令适用的要求。
The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.	制造商必须遵守第17条的规定，在产品上附加CE标识，并出具一份书面符合性声明。此声明应涵盖一种或多种已生产的、标识了产品名称、产品代码或其他明确标识的医疗器械。该符合性声明必须由制造商保存。
3. Quality system	3．质量体系
3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.	3.1．制造商必须向公告机构提出质量体系评估的申请。
The application must include:	该申请必须包括：
— the name and address of the manufacturer and any additional manufacturing site covered by the quality system,	—制造商的名称和地址及质量体系所覆盖的额外制造地点，
— all the relevant information on the product or product category covered by the procedure,	—所有本程序所涵盖的与产品或产品类别相关的资料，
— a written declaration that no application has been lodged with any other notified body for the same product-related quality system,	—同一产品相关质量体系未向其他任何公告机构提出申请的书面声明，
— the documentation on the quality system,	—质量体系文件，
— an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved,	—制造商履行经批准的质量体系所加诸的义务的保证，
— an undertaking by the manufacturer to keep the approved quality system adequate and efficacious,	—制造商保持经批准的质量体系的充分性和有效性的保证，
— _M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: _	—制造商应建立系统化程序并随时予以更新，以评审器械的生产后相关经验，包括附录X中所述的规定并设法采取必须的纠正措施的承诺。本项承诺还须包括制造商在获悉下列事故时立即通知主管当局的义务：
(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;	（i）器械的特性和/或性能异常或损坏,以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的使用说明。
(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.	（ii）与器械的特性及/或性能有关的技术上或医学上的原

3.2. Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular the corresponding documentation, data and records arising from the procedures referred to in point (c). It shall include in particular an adequate description of: (a) the manufacturer's quality objectives; (b) the organization of the business and in particular: — the organizational structures, the responsibilities of the managerial staff and their organizational authority where quality of design and manufacture of the products is concerned, — the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of design and of product, including control of products which fail to conform, — where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party; (c) the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular: — a general description of the product, including any variants planned, and its intended use(s), — the design specifications, including the standards which will be applied and the results of the risk analysis, and also a description of the solutions adopted to fulfil the essential requirements which apply to the products if the standards referred to in Article 5 are not applied in full, — the techniques used to control and verify the design and the processes and systematic measures which will be used when the products are being designed, — if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified	因，导致(i)项中所述的情形，致使制造商系统地召回同型号的器械。 3.2. 质量体系的实施应确保产品从制造阶段至最终检验皆符合本指令适用的要求。制造商应将其质量体系所采用的所有要素、要求及规定，系统地通过有序的方式以书面的方针及程序建立档案，如质量程序、质量计划、质量手册和质量记录。 该档案特别应包括由（c）点中提到的程序所产生的相应文件、数据和记录。 该档案特别应包括对以下内容的充分描述： （a）制造商的质量目标； （b）商业组织，特别是： —与相关产品设计及制造品质有关的组织架构，管理层责任及权限， —监测品质系统有效运作的方法，特别是使产品及设计的质量达到预定的质量，包括对不合格品的控制方法； —如果产品的设计、制造和/或最终检查和测试是由第三方完成，对质量体系的有效运行进行监控的方法，尤其对第三方所施加的控制的类型和程度； （c）对产品的设计进行监视和验证的程序，包括相应的文件，特别是： —对产品的大体描述，包括任何计划中的改变及其预期用途； —设计规范，包括应用的标准及风险分析的结果，及产品未完全采用第5条所提到的标准时，须叙述为符合基本要求所采取的解决方法；

by the manufacturer, — a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device, — a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Commission Directive 2003/32/EC (1), — the solutions adopted as referred to in Annex I, Chapter I, Section 2, — the pre-clinical evaluation, — the clinical evaluation referred to in Annex X, — the draft label and, where appropriate, instructions for use. (d) the inspection and quality assurance techniques at the manufacturing stage and in particular: — the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents, — the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture; (e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration of the test equipment adequately. 3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the	—用于控制及验证设计的技术及产品设计时使用的程序和系统化方法； —如果器械须和其他器材连接以便依其预期目的运行，应证明器械在与具有制造商指定之特性的其他器材连接后仍符合基本要求； —说明器械是否与附录I第7.4点提及的物质或人血衍生物联合而成为整体，在考虑该器械预期目的后，提供对此结合体所要求的关于评估该物质或人血衍生物的安全、质量和有用性的试验资料； —说明器械是否使用委员会2003/32/EC指令中所提及的动物源性组织制造而成； —附录I第一章第二部分所叙述的解决方案； —临床前评价； —附录X中所述的临床评价； —标签草案，适当时包括使用说明书。 （d）制造阶段的检验及质量保证技术，特别是： —欲使用的过程和程序，特别是有关灭菌、采购及相关文件； —依每阶段的制造过程图样、规范或其他相关文件所制定的产品识别程序，此程序应与上述过程图样、规范或其他相关文件保持随时更新。 （e）制造前、制造中及制造后执行的适当测试及试验，执行的频率及使用的试验设备；另外，必须能充分地追溯试验设备的校正状况。 3.3．公告机构必须审核前述质量体系，以判定该质量体系是否符合第3.2点所述的要求。如果质量体系采用相关的协

manufacturing processes. The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment. 3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment. 4. Examination of the design of the product 4．产品设计审查 4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the product which he plans to manufacture and which falls into the category referred to in Section 3.1. 4.2. The application must describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this Directive, as referred to in Section 3.2 (c). 4.3. The notified body must examine the application and, if the product conforms to the relevant provisions of this Directive, issue the application with an EC design-examination certificate. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of the Directive. The certificate must contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the product. In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The	调标准，则应假定其符合这些标准要求。 评估小组成员应至少包含一位对所评估相关产品技术有经验的评审人员，评估程序应包括相关产品设计文档，制造商工厂，适当时，到其供应商和/或分包商工厂对生产过程进行检查。 检查结果应通知制造商。通知内容必须包括检查结论和合理的评估。 3.4．对于任何有关质量体系或涵盖的产品范围的具体变更计划，制造商应通知批准其质量体系的公告机构。公告机构应评估这些更动事项，以决定变更后的质量体系是否仍然符合3.2点的要求。公告机构则必须将最终决议通知制造商。该决议内容必须包括检查结论及合理的评估。 4．产品设计审查 4.1．除了第3点规定的义务外，制造商应向公告机构提出与产品相关的设计文档审查申请，该设计文档须和制造商计划制造、且符合第3.1点分类的产品有关。 4.2．申请时应描述相关产品的设计、制造及性能。并应包括评估该产品是否符合本指令第3.2(a)点所述要求所需的文件。 4.3．公告机构应审查申请资料，如果产品符合本指令的相关规定，则公告机构应就该申请核发EC设计审查证书，如有需要，公告机构可要求申请者完成进一步测试或证明，以便评估是否符合本指令规定。 证书应包括审查结论，证书的有效条件，辨识经批准的设计所需的证明资料及，适当时，产品预期目的的描述。 对于附录 I 第 7.4 点第 2 段所提到的器械，公告机构应先就

notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned. In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA. In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive. 4.4. Changes to the approved design must receive further approval from the notified body which issued the EC design-examination certificate wherever the changes could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product. The applicant shall inform the notified body which issued the EC design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the EC designexamination certificate. 5. Surveillance 5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system. 5.2. The manufacturer must authorize the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular: — the documentation on the quality system, — the data stipulated in the part of the quality system relating to design, such as the results of analyses, calculations, tests, the solutions adopted as referred to in Annex I, Chapter I, Section 2, pre-clinical and clinical evaluation, post-market clinical follow-up plan and the results of the post-market clinical follow-up, if applicable, etc., — the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc. 5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the	该部分所讨论的方面向各成员国依 2001/83/EC 号指令或 EMEA 指定的主管当局之一提出咨询后，再做决定。主管当局或 EMEA 必须在接到有效文档后 210 日内提出意见草案。国家主管当局或 EMAM 的科学意见必须包含于器械相关的文档中。公告机构将在做出自己的决定时对本磋商结果中表达的观点给予应有的考虑。 对于附录I第7.4点第2段所提到的器械，国家主管当局或EMAM的科学意见必须包含于器械相关的文档中。主管当局或EMEA必须在接到有效文档后210日内提出意见草案。公告机构将在做出自己的决定时对本磋商结果中表达的观点给予应有的考虑。如果EMAM的科学意见是否定的，公告机构将不会发放证书。公告机构将向EMAM转达他的最终决定。 如果产品由指令2003/32/EC中所述的动物源性组织制造而成，则公告机构必须遵守本指令中所述的程序。 4.4．对经批准的设计的任何更改，如果该更改会影响本指令基本要求的符合性，或所描述的产品使用条件的符合性，则申请者必须通知签发EC设计审查证书的公告机构以得到进一步批准。申请者应向签发EC设计审查证书的公告机构通报任何此类对已批准设计的更改。这种额外批准必须采取在原EC设计审查证书上另外附加批准文件的形式。 5．监督 5.1．监督的目的在于确保制造商充分履行其经批准的质量体系所引发的责任。 5.2．制造商应授权公告机构执行所有必要的检验，并提供所有有关的资料，特别是下列各项：

manufacturer applies the approved quality system and must supply the manufacturer with an assessment report. 5.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report. 6. Administrative provisions 6.1. _M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, keep at the disposal of the national authorities: _ — the declaration of conformity, — the documentation referred to in the fourth indent of Section 3.1_M5 and in particular the documentation, data and records referred to in the second paragraph of Section 3.2 _, — the changes referred to in Section 3.4, — the documentation referred to in Section 4.2, and — the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.3 and 5.4. 7. Application to devices in Classes IIa and IIb. 7.1. In line with Article 11(2) and (3), this Annex may apply to products in Classes IIa and IIb. Section 4, however, does not apply. 7.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device subcategory for compliance with the provisions of this Directive. 7.3. For devices in Class IIb the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each generic device group for compliance with the provisions of this Directive. 7.4. In choosing representative sample(s) 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	—质量体系文件； —质量体系的相关部分所规定的与设计有关的数据，适当时，如分析、结论、测试、所采取的如附录I第1章第2部分所叙述的解决方案、临床前和临床评价、上市后临床随访计划及其结果，等等； —质量体系的相关部分所规定的与制造有关的数据，如检验报告及测试资料、校准资料、相关人员资格审核报告，等等。 5.3．公告机构必须定期执行适当的检验及评估，以确保制造商能应用经批准的质量体系，并应向制造商提供评估报告。 5.4．此外，公告机构可对制造商进行突击性访查。在此类访查中，公告机构于必要时可自行或要求制造商检查其质量体系，以确认该体系运行正常。公告机构必须向制造商提供访查报告，如果执行测试，则应另外附上测试报告。 6．管理规定 6.1．制造商或其授权代表必须，在最后一批产品生产后至少5年内，如果是可植入器械则至少15年内，保存如下文件供主管当局查阅： —符合性声明， —第3.1 点第4小项所述的文件，以及特别是第3.2点第2段所述的数据和记录， —第3.4点所述的更改， —第4.2点所述的文件，和， —第3.3、4.3、4.4、5.3和5.4点中所述的来自公告机构的决议和报告。

previous relevant assessments (e.g. with regard to physical, chemical or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken. 7.5. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 5. 8. Application to the devices referred to Article 1(4a) Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with _M5 Article 114(2) of Directive 2001/83/EC _.	7．IIa类和IIb类器械的应用 7.1．依据第11条第（2）款和第（3）款的要求，本附录可以应用于IIa类和IIb类产品。但是第4部分不适用。 7.2．对于IIa类器械，作为第3.3部分中的评估的一部分，公告机构应该对每一亚类的器械选取至少一个代表性样本，评估第3.2点中描述的技术文档，以判定对本指令规定的符合性。 7.3．对于IIb类器械，作为第3.3部分中的评估的一部分，公告机构应该对每一个同类器械组选取至少一个代表性样本，评估第3.2（c）点中描述的技术文档，以判定对本指令规定的符合性。 7.4．在选择代表性样本时，公告机构应考虑工艺的先进性、类似的设计、工艺、制造和灭菌方法、预期用途和任何此前依据本指令而开展的相关评估（如，关于物理、化学或生物学特性的评估）。公告机构应向主管当局书面说明其所选择样本的理由。 7.5．作为第5部分所述的监督评估的一部分，公告机构将评估额外的样本。 8．第1条第（4a）款所述器械的应用 为完成第1条第（4a）款所述的每一批器械的制造，制造商应通知公告机构该批器械的放行，并向公告机构提交该批产品中所使用的人血衍生物的官方证书，该证书必须由国家实验室或由成员国依据2001/83/EC指令第114条第（2）款而指定的实验室签发。
ANNEX III **EC TYPE-EXAMINATION**	**附录III** **EC 型式检验**

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Directive.	1. EC型式检验是一种程序，公告机构借此程序确认并证明代表制造过程的样品符合本指令相关规定。
2. The application includes:	2. 申请时应提出下列资料：
— the name and address of the manufacturer and the name and address of the authorized representative if the application is lodged by the representative,	—制造商的名称和地址，如果是由授权代表提出申请，则必须另外提出授权代表的名称和地址，
— the documentation described in Section 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Directive. The applicant must make a 'type' available to the notified body. The notified body may request other samples as necessary,	—第3点所述的评价代表相关制造过程的样品符合本指令的要求所需的文件，此样品以下称"型式"。 申请者应向公告机构提交一个"型式"。必要时，公告机构可要求制造商提供其他样品。
— a written declaration that no application has been lodged with any other notified body for the same type.	—未向其他任何公告机构就相同型式提出申请的书面声明。
3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:	3. 制造商提供的文件应便于了解产品的设计、制造及功能，且须特别包含下列资料：
— a general description of the type, including any variants planned, and its intended use(s),	—对型式的大体描述，包括任何计划中的更改及其预期用途，
— design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc.,	—设计图样、制造方法，特别是有关灭菌的方法，及零件、装配组件、电路等的图形，
— the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,	—使上述图形和图样及产品操作易于了解的解释及说明，
— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 5 have not been applied in full,	—有关指令第5条所列标准全部或部分适用的情形，若未全部采第5条的标准，则须叙述为符合基本要求所采取的解决方法，
— the results of the design calculations, risk analysis, investigations, technical tests, etc. carried out,	—已执行的设计计算、风险分析、调查、技术测试等的结果，
— a statement indicating whether or not the device incorporates, as an integral part, a substance, or human blood derivative, referred to in Section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance, or human blood derivative, taking account of the intended purpose of the device,	—表明器械是否含有附录I第7.4点提及的物质或人血衍生物而作为一个整体的说明，以及考虑到该器械的预期目的，由于这种联合而所需的为了评估该物质或人血衍生物的安
— a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC,	
— the solutions adopted as referred to in Annex I, Chapter I, Section 2,	

— the pre-clinical evaluation, — the clinical evaluation referred to in Annex X, — the draft label and, where appropriate, instructions for use. 4. The notified body must: 4.1. examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the items designed in conformity with the applicable provisions of the standards referred to in Article 5, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards; 4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer; 4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied; 4.4. agree with the applicant on the place where the necessary inspections and tests will be caried out. 5. If the type conforms to the provisions of this Directive, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body. In the case of devices referred to in Annex I, Section 7.4, second paragraph, the notified body shall, as regards the aspects referred to in that section, consult one of the authorities designated by the Member States in accordance with Directive 2001/83/EC or the EMEA before taking a decision. The opinion of the competent national authority or the EMEA must be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the competent national authority or the EMEA must be included in the documentation concerning the device. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will	全性、质量和有用性所作测试的数据。 —表明器械是否用2003/32/EC指令中所述的动物源性组织生产而成的说明， —依据附录I第1章第2点而采取的解决方案， —临床前评价， —附录X所述的临床评价， —标签草案，适当时，使用说明书。 4．公告机构必须： 4.1．审核和评估文件，并确认该型式的制造符合文件的叙述；并记录依据第5条所述的标准相关规定所指定的项目；同时记录基于以上所提及标准的相关规定的非指定的项目。 4.2．执行或安排适当的检验及必要的测试，以验证制造商在未选用第5条相关标准时，所采用的解决方法是否符合本指令的基本要求；如果器械需与其他器材连接才能达到预期的运行，要求制造商提供相关资料证明该器械在与其他具有制造商规定性质的器材连接时符合基本要求的规定； 4.3．执行或安排适当的检验及必要的测试，以查证制造商决定选用相关标准时是否确实被应用； 4.4．同意申请者提出的开展必要检验及测试的地点。 5．型式符合本指令规定时，公告机构应发给申请者EC型式检验证明。该证明必须包含制造商的名称及地址、检验结论、有效性条件和识别已批准的型式所需的资料。文件的相关资料应附于证明之后，并由公告机构保留一份拷贝。 对于附录I第7.4第2段所述的器械，依据该部分所述的方面，公告机构在做出决定前应与成员国依 2001/83/EC号指令

convey its final decision to the competent body concerned. In the case of devices referred to in Annex I, Section 7.4, third paragraph, the scientific opinion of the EMEA must be included in the documentation concerning the device. The opinion of the EMEA must be drawn up within 210 days after receipt of valid documentation. The notified body will give due consideration to the opinion of the EMEA when making its decision. The notified body may not deliver the certificate if the EMEA's scientific opinion is unfavourable. It will convey its final decision to the EMEA. In the case of devices manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the notified body must follow the procedures referred to in that Directive. 如果产品由指令2003/32/EC中所述的动物源性组织制造而且，在公告机构必须遵守本指令中所述的程序。 6. The applicant must inform the notified body which issued the EC typeexamination certificate of any significant change made to the approved product. Changes to the approved product must receive further approval from the notified body which issued the EC type-examination certificate wherever the changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product. This new approval must, where appropriate, take the form of a supplement to the initial EC typeexamination certificate. 7. Administrative provisions 7.2. Other notified bodies may obtain a copy of the EC type-examination certificates and/or the supplements thereto. The Annexes to the certificates must be made available to other notified bodies on reasoned application, after the manufacturer has been informed. 7.3. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least five years after the last device has been manufactured. In the case of implantable devices, the period shall be at least 15 years after the last product has been manufactured.	成立的主管机构或EMEA进行磋商。主管当局或EMEA必须在接到有效文档后210日内提出意见草案。国家主管当局或EMAM的科学意见必须包含于器械相关的文档中。公告机构将在做出自己的决定时对本磋商结果中表达的观点给予应有的考虑。 对于附录I第7.4点第3段所提到的器械，国家主管当局或EMAM的科学意见必须包含于器械相关的文档中。主管当局或EMEA必须在接到有效文档后210日内提出意见草案。公告机构将在做出自己的决定时对本磋商结果中表达的观点给予应有的考虑。如果EMAM的科学意见是否定的，公告机构将不会发放证书。公告机构将向EMAM转达他的最终决定。 如果产品由指令2003/32/EC中所述的动物源性组织制造而且，在公告机构必须遵守本指令中所述的程序。 6．经批准的产品有任何重大的改变时，申请者应将此改变通知签发EC型式检验证明的公告机构。 前述的改变若足以影响基本要求的符合性或产品预定的使用条件时，必须经过签发EC型式检验证明的公告机构的额外批准。适当时，新的批准必须以补充文件的形式附加于原EC形式检验证明之后。 7．管理规定 7.2．在其他公告机构提出要求时，公告机构应提供有关EC型式检验证明和/或其补充文件。在通知制造商后，其他公告机构基于合理的申请，必须可以得到证明的附件。 7.3．制造商或其授权代表应保存EC型式检验证明及其附件的技术文件拷贝到最后一批器械生产后至少5年。如果是可

	植入器械，则保存到最后一批器械生产后至少15年。
ANNEX IV **EC VERIFICATION**	**附录IV** **EC确认**
1. EC verification is the procedure whereby the manufacturer or his authorized representative _M5_____ _ ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the EC type-examination certificate and meet the requirements of this Directive which apply to them.	1．EC确认是一种程序，制造商或其授权代表借此程序确保并宣称，适用于第4点所设定的程序的产品，与EC型式检验证明中所述的型式一致，并满足本指令中对其适用的要求。
2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of the Directive which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, pre-established provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer must affix the CE marking in accordance with Article 17 and draw up a declaration of conformity. In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 4.	2．制造商应采取所有必要的措施，以确保其制造过程制造出来的产品符合EC型式检验证明所述的型式及本指令中对其适用的要求。制造商在制造前应准备定义制造过程，特别是有关必要的灭菌过程的文件以及为确保制造均质产品和，适当时，确保产品符合EC型式检验证明上所载型式及符合本指令适用的要求所实施的例行程序及既定的条款。制造商应依第17条的规定在产品上附加CE标识并起草一份符合性声明。 除此之外，对于以无菌状态上市的产品，以及那些仅与设计用于确保和维持无菌状态的制造过程有关的方面，制造商必须遵循附录V第3和第4点的规定。
3. The manufacturer must undertake to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons	3．制造商必须实施并更新一个系统性的程序，以评审器械于制造后所获得的经验，包括附录X所述的规定，从而执行适当的纠正措施。制造商还有义务在得知下列事故时立即通知主管当局： （i）器械的特性和/或性能异常或损坏，以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的标签或使用说明； （ii）任何与器械的特性和/或性能有关的，在（i）中所述的技术上或医学上的原因，导致制造商有系统召回同型号的

referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.	器械。
4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides. The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.	4．公告机构应执行适当的检验及测试以证实产品符合本指令的要求，制造商可选择依第5点规定对每一个产品进行检验及测试，也可选择依据依第6点所述的统计学基础检验及测试产品。 上述的检查不适用于设计用于确保无菌状态的制造过程。
5. Verification by examination and testing of every product	5．通过产品的逐个检验和测试进行确认
5.1. Every product is examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out in order to verify, where appropriate, the conformity of the products with the EC type described in the type-examination certificate and with the requirements of the Directive which apply to them.	5.1．所有产品应经过逐一地检验，并对其执行第5条相关标准中所规定的适当的测试，或同等效力的测试，以便在适当时验证产品符合EC型式检验证明所描述的型式，以及指令对其适用的要求。
5.2. The notified body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.	5.2．公告机构必须在每一个批准的产品上附加或请制造商附加其识别号码，并起草一份书面的关于已开展测试的符合性证书。
6. Statistical verification	6．统计学确认
6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.	6.1．制造商必须将产品以整齐均质的批数提交。
6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the EC type-examination certificate and with the requirements of the Directive which apply to them in order to determine whether to accept or reject the batch.	6.2．从每批产品中随机抽样，对样本中的每个产品进行逐个地检验，并执行第5条相关标准中所订的适当的测试或同等效力的测试，以便在适当时，验证产品符合EC型式检验证明所描述的型式，已及指令对其适用的要求，从而决定接受或拒绝该批产品。
6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the harmonised standards referred to in Article 5, taking account of the specific nature of the product categories in question.	6.3．产品应依其属性和/或变量执行统计控制，使抽样计划能根据当时的技术发展状态，符合确保高水平的安全和性能的操作特性。应在考虑相关产品类别的特性的同时，依第五条相关调和标准的规定建立抽样计划。
6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.	6.4．如果该批可接受，公告机构应在每个产品上附加或要

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification. The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process. 7. Administrative provisions _M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: _ — the declaration of conformity, — the documentation referred to in Section 2, — the certificates referred to in Sections 5.2 and 6.4, — where appropriate, the type-examination certificate referred to in Annex III. 8. Application to devices in Class IIa In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following _M5_____ _: 8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them; 8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified body are intended to confirm the conformity of the products in Class IIa with the technical documentation referred to in Section 3 of Annex VII. 9. Application to devices referred to in Article 1(4a) In the case of section 5, upon completing the manufacture of each batch of devices referred to in Article 1(4a), and in the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in	求制造商附加其识别号码，并起草一份书面的关于已开展测试的符合性证书。除了样品中发现为不符合的产品外，该批其余的产品均可上市。 如果该批被拒绝，公告机构应采取适当的措施以防止该批产品上市。若产品经常被拒绝，公告机构可暂停统计学确认。 制造商出于对公告机构的责任，可以在制造过程中附加公告机构的识别号码。 7．管理规定 制造商或其授权代表必须将下列资料从最后一批产品制造后保存至少5年，如果是可植入器械，则至少15年，以供政府当局查阅： —符合性声明， —第2部分中所述的文档， —第5.2和6.4部分中所述的证书， —适当时，附录III所述的型式检验证书。 8．IIa类器械的应用 依据第11条第（2）款的规定，本附录适用于IIa类产品，适用于下列情形： 8.1．排除第1及第2点的规定，制造商借符合性声明确保并宣称其IIa类的产品依据附录VII第3点的技术文档制造，并符合本指令对其适用的要求； 8.2．排除第1、2、5及6点的规定，公告机构执行的确认是为了确定IIa类产品与附录VII第3点所述的技术文档的符合性。 9．对第1条第（4a）款所述器械的应用

accordance with _M5 Article 114(2) of Directive 2001/83/EC _.	在第5点中，为完成第1条第（4a）款所述的每一批器械的制造，或在第6点中，制造商应通知公告机构该批器械的放行，并向公告机构提交该批产品中所使用的人血衍生物的官方证书，该证书必须由国家实验室或由成员国依据2001/83/EC指令第114条第（2）款而指定的实验室签发。
ANNEX V **EC DECLARATION OF CONFORMITY** **(Production quality assurance)**	**附录V** **EC 符合性声明** **（生产质量保证）**
1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in Section 3, and is subject to the Community surveillance referred to in Section 4.	1．制造商应确保在相关产品的制造过程中施行经批准的质量体系，并依据第3点执行最终检验，依据第4点所述接受共同体监督。
2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them.	符合性声明是制造商为完成第1点义务，确保并声明相关产品符合EC型式检验证书所载之型式，并满足本指令对其适用要求的程序之一。
The manufacturer must affix the CE marking in accordance with Article 17 and draw up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer.	制造商必须依据第17条规定在产品上附加CE标识，并起草一份符合性声明。本项声明应涵盖一种或多种已制造的产品，这些产品应通过产品名称、产品编码或其他清晰的标记能够被明显识别。此声明应由制造商保管。
3. Quality system	3．质量体系
3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.	3.1. 制造商应向一个公告机构提出其质量体系的评估申请。
The application must include:	评估申请必须包括以下内容：
— the name and address of the manufacturer,	—制造商的名称和地址，
— all the relevant information on the product or product category covered by the procedure,	—本程序涵盖的所有与产品或产品类别相关的信息，
— a written declaration that no application has been lodged with any other notified body for the same products,	—针对相同产品未向其他任何公告机构提出申请的书面声明，
— the documentation on the quality system,	—质量体系文档，
— an undertaking to fulfil the obligations imposed by the quality system is approved,	
— an undertaking to maintain the practicability and effectiveness of the approved quality system,	

— where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,	—履行经批准的质量体系所规定的义务的保证，
— _M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: _	—保持经批准的质量体系的实用性及有效性的保证，
(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;	—适用时，已批准型式的技术文档以及EC型式检验证书的拷贝，
(ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) above leading to a systematic recall of devices of the same type by the manufacturer.	制造商必须实施并更新一个系统性的程序，以评审器械于制造后所获得的经验，包括附录X所述的规定，从而执行适当的纠正措施。制造商还有义务在得知下列事故时立即通知主管当局：
3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.	（i）器械的特性和/或性能异常或损坏，以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的标签或使用说明；
All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must permit uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.	（ii）任何与器械的特性和/或性能有关的，在（i）中所述的技术上或医学上的原因，导致制造商有系统召回同型号的器械。
It must include in particular an adequate description of:	3.2. 质量体系的应用必须确保产品符合EC型式检验证书上所载的型式。
(a) the manufacturer's quality objectives;	制造商为其质量体系所采用的要素、要求及规定必须以系统化、有秩序的方式以书面方针声明及程序建立档案。该质量体系文档必须允许对质量方针和程序，如质量安排、计划、手册和记录，有一个统一的解释。
(b) the organization of the business and in particular:	该档案特别应包括对以下方面的充分描述：
— the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,	（a）制造商的质量目标；
— the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of product, including control of products which fail to conform,	（b）商业组织，特别是：
— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and	—与相关产品设计及制造品质有关的组织架构，管理阶层责任及权限，
	—监测品质系统有效运作的方法，特别是使产品质量达到

extent of control applied to the third party; (c) the inspection and quality assurance techniques at the manufacturing stage and in particular: — the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents, — the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture; (d) the appropriate tests and trials to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment. 3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes. The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment. 3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. After the abovementioned information has been received the decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment. 4. Surveillance 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system. 4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with	预定的质量，包括对不合格品的控制方法； —如果产品的制造和/或最终检查和测试是由第三方完成，对质量体系的有效运行进行监控的方法，尤其对第三方所施加的控制的类型和程度； （c）制造阶段的检验及质量保证技术，特别是： —欲使用的过程及程序，特别是有关灭菌、采购及相关文件， —依每阶段的制造过程图样、规范或其他相关文件所制定的产品识别程序，此程序应与上述过程图样、规范或其他相关文件保持随时更新。 （d）制造前、制造中及制造后执行的适当测试及试验，执行的频率及使用的试验设备；另外，必须能充分地追溯试验设备的校正状况。 3.3. 公告机构必须审核前述质量体系，以判定该质量体系是否符合第3.2点所述的要求。如果质量体系采用相关的协调标准，则应假定其符合这些标准要求。 评估小组成员应至少包含一位对所评估相关产品技术有经验的评审人员，评估程序应包括经制造商允许的检查，以及在适当情况下，在制造商的供应商允许下，对其供应商进行生产过程检查。 最终检查结束后必须将检查结果通知制造商。通知内容必须包括检查结论和合理的评估。 3.4. 对于任何有关质量体系的具体变更计划，制造商应通知批准其质量体系的公告机构。公告机构应评估这些更动事项，以决定变更后的质量体系是否仍然符合3.2点的要求。接到上述信息后，公告机构做出的评估决定应通知制造商。

all relevant information, in particular:	通知内容必须包括检查结论和合理的评估。
— the documentation on the quality system,	4．监督
— the technical documentation,	4.1．监督的目的在于确保制造商充分履行其经批准的质量体系所引发的责任。
— the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	4.2．制造商应授权公告机构执行所有必要的检查，并提供所有有关的资料，特别是下列各项：
4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.	—质量体系文件，
4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.	—技术文档，
5. Administrative provisions	—质量体系的相关部分所规定的与制造有关的资料，如检查报告和测试数据，校准数据，相关人员资格报告，等等。
5.1. _M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: _	4.3．公告机构必须定期执行适当的检验及评估，以确保制造商能应用经批准的质量体系，并应向制造商提供评估报告。
— the declaration of conformity,	4.4．此外，公告机构可对制造商进行突击性访查。在此类访查中，公告机构于必要时可自行或要求制造商检查其质量体系，以确认该体系运行正常。公告机构必须向制造商提供访查报告，如果执行测试，则应另外附上测试报告。
— the documentation referred to in the fourth indent of Section 3.1,	5．管理规定
— the changes referred to in Section 3.4,	5.1．制造商或其授权代表必须，在最后一批产品生产后至少5年内，如果是可植入器械则至少15年内，保存如下文件供主管当局查阅：
— the documentation referred to in the seventh indent of Section 3.1,	—符合性声明，
— the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,	—第3.1点第4小项所述的文件，
— where appropriate, the type-examination certificate referred to in Annex III.	—第3.4点所述的更改，
6. Application to devices in Class IIa	—第3.1点第7小项所述的文件，
In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:	—第4.3和4.4点中所述的来自公告机构的决议和报告。
6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to	

them. 6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive. 6.3. In choosing representative sample(s) 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 or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken. 6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3. 7. Application to devices referred to in Article 1(4a) Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with _M5 Article 114(2) of Directive 2001/83/EC _.	一适当时，附录III所述的型式检验证书。 6．IIa类器械的应用 依据第11条第（2）款的要求，本附录可以应用于IIa类产品，满足下列要求： 6.1．排除第2、3.1及3.2 点的规定，制造商借符合性声明确保并宣称其属于IIa类的产品按照附录VII第3点所述的技术文件制造，并符合本指令对其适用的要求； 6.2．对于IIa类器械，作为第3.3部分中的评估的一部分，公告机构应该对每一个同类器械组选取至少一个代表性样本，评估附录VII第3点中描述的技术文档，以判定对本指令规定的符合性。 6.3．在选择代表性样本时，公告机构应考虑工艺的先进性、类似的设计、工艺、制造和灭菌方法、预期用途和任何先前的依据本指令而开展的相关评估（如，关于物理、化学或生物学特性的评估）。公告机构应向主管当局书面说明其所选择样本的理由。 6.4．作为第4.3部分所述的监督评估的一部分，公告机构将评估额外的样本。 7．第1条第（4a）款所述器械的应用 为完成第1条第（4a）款所述的每一批器械的制造，制造商应通知公告机构该批器械的放行，并向公告机构提交该批产品中所使用的人血衍生物的官方证书，该证书必须由国家实验室或由成员国依据2001/83/EC指令第114条第（2）款而指定的实验室签发。
ANNEX VI **EC DECLARATION OF CONFORMITY**	**附录VI** **EC 符合性声明**

(Product quality assurance)	（产品质量保证）
1. The manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified in Section 3 and must be subject to the surveillance referred to in Section 4. In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex V, Sections 3 and 4.	1．制造商必须确保依据第3点规定在产品最终检验及测试上施行经批准的质量体系，并依第4点所述接受监督。 除此之外，对于以无菌状态上市的产品，以及那些仅与设计用于确保和维持无菌状态的制造过程有关的方面，制造商必须遵循附录V第3和第4点的规定。
2. The EC declaration of conformity is the part of the procedure whereby the manufacturer who fulfils the obligations imposed by Section 1 ensures and declares that the products concerned conform to the type described in the EC type-examination certificate and meet the provisions of this Directive which apply to them. The manufacturer affixes the CE marking in accordance with Article 17 and draws up a written declaration of conformity. This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body which performs the tasks referred to in this Annex.	2．EC 符合性声明是一种程序，符合第1点义务的制造商借此程序确保并声明相关产品符合指令适用的要求。 制造商必须遵守第17条的规定，在产品上附加CE标识，并出具一份书面符合性声明。此声明应涵盖一种或多种已生产的、标识了产品名称、产品代码或其他明确标识的医疗器械。该符合性声明必须由制造商保存。CE标识之后必须附有执行本附录所述任务的公告机构的识别号码。
3. Quality system 3.1. The manufacturer lodges an application for assessment of his quality system with a notified body. The application must include: — the name and address of the manufacturer, — all the relevant information on the product or product category covered by the procedure, — a written declaration specifying that no application has been lodged with any other notified body for the same products, — the documentation on the quality system, — an undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved, — an undertaking by the manufacturer to keep the approved quality system adequate and efficacious, — where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates,	3．质量体系 3.1．制造商必须向公告机构提出质量体系评估的申请。 该申请必须包括： —制造商的名称和地址， —所有本程序所涵盖的与产品或产品类别相关的资料， —同一产品相关质量体系未向其他任何公告机构提出申请的书面声明， —质量体系文件， —制造商履行经批准的质量体系所加诸的义务的保证， —制造商保持经批准的质量体系的充分性和有效性的保证， —适当时，已批准型式的技术文档和EC型式检验证书的拷贝，

— _M5 an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: _ (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (i) leading to a systematic recall of devices of the same type by the manufacturer.	—制造商建立并系统化程序并随时予以更新，以评审器械的生产后相关经验，包括附录X中所述的规定并设法采取必须的纠正措施的承诺。本项承诺还须包括制造商在得知下列事件时立即通知主管当局的义务：（i）器械的特性和/或性能异常或损坏，以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的使用说明。（ii）与器械的特性及/或性能有关的技术上或医学上的原因，导致(i)项中所述的情形，致使制造商系统地召回同型号的器械。
3.2. Under the quality system, each product or a representative sample of each batch is examined and the appropriate tests defined in the relevant standard (s) referred to in Article 5 or equivalent tests are carried out to ensure that the products conform to the type described in the EC type-examination certificate and fulfil the provisions of this Directive which apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality programmes, quality plans, quality manuals and quality records.	在质量体系之下，每批产品或每批产品的代表性样品应加以检测，并开展第5条所述相关标准规定的适当的测试或同等效力的测试，以确保该产品符合EC型式检验证书所载的型式及本指令对其适用的规定。制造商应将其质量体系所采用的所有要素、要求及规定，系统地通过有序的方式以书面的措施、程序及说明建立档案。该质量体系文档必须允许对质量安排、质量计划、质量手册和质量记录有一个统一的解释。
It must include in particular an adequate description of:	文件内容应特别包括下列各项适当的描述：
— the quality objectives and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality,	—与产品质量有关的质量目标及组织结构和管理阶层责任与权限，
— the examinations and tests that will be carried out after manufacture; it must be possible to trace back the calibration of the test equipment adequately,	—制造后欲开展的检查及测试；另应能正确地追溯试验设备的校准状况，
— the methods of monitoring the efficient operation of the quality system,	—监测质量体系有效运作的方法，
— the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.,	—有关检验、测试、校准及相关人员资格证书等质量记录，
— where the final inspection and testing of the products, or elements thereof, are carried out by a third party, the	—如果产品或配件的最终检查和/或测试是由第三方完成，对质量体系的有效运行进行监控的方法，尤其对第三方所

methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party. The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility. 3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to inspect the manufacturing processes. The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment. 3.4. The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether after these changes the quality system will still meet the requirements referred to in Section 3.2. After receiving the abovementioned information it must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment. 4. Surveillance 4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system. 4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage locations and supply it with all relevant information, in particular: — the documentation on the quality system, — the technical documentation, — the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.	施加的控制的类型和程度。 上述的检查不适用于那些设计用于确保无菌状态的制造过程。 3.3. 公告机构必须审核前述质量体系，以判定该质量体系是否符合第3.2点所述的要求。如果质量体系采用相关的协调标准，则应假定其符合这些标准要求。 评估小组成员应至少包含一位对所评估相关产品技术有经验的评审人员，评估程序应包括经制造商允许的检查，以及在适当情况下，在制造商的供应商允许下，对其供应商进行生产过程检查。 最终检查结果必须通知制造商。通知内容必须包括检查结论和合理的评估。 3.4. 对于任何有关质量体系的具体变更计划，制造商应通知批准其质量体系的公告机构。 公告机构应评估这些更改事项，以决定变更后的质量体系是否仍然符合3.2点的要求。 接到上述信息后，公告机构做出的评估决定应通知制造商。通知内容必须包括检查结论和合理的评估。 4. 监督 4.1. 监督的目的在于确保制造商充分履行其经批准的质量体系所引发的责任。 4.2. 制造商必须允许公告机构为了开展检查而进入与检查、测试和贮存有关的场所，并提供所有的相关资料，特别是下列各项： —质量体系文件， —技术文档，

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must supply the manufacturer with an assessment report.	一质量记录，如检查报告、测试数据、校准数据和相关人员资格报告等等。
4.4. In addition, the notified body may pay unannounced visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the requirements of the Directive which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standard(s) referred to in Article 5 or equivalent tests must be carried out. Where one or more of the samples fails to conform, the notified body must take the appropriate measures.	4.3．公告机构必须定期执行适当的检验及评估，以确保制造商能应用经批准的质量体系，并应向制造商提供评估报告。
It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.	4.4．此外，公告机构可对制造商进行突击性访查，以检查质量体系是否正常运行，并检查产品符合本指令对其适用的要求。访查结束时，公告机构必须对在现场从最终产品抽取的一个合理样本，依据第5条所述的相关标准规定，开展检测和适当的测试，或者执行同等的测试。如果有一个或多个样品不合格，在公告机构必须采取适当的措施。 必须向制造商提供检查报告，如果开展了测试，还必须提供测试报告。
5. Administrative provisions	5．管理规定
5.1. _M5 The manufacturer or his authorised representative must, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last product has been manufactured, make available to the national authorities: _	5.1．制造商或其授权代表必须，在最后一批产品生产后至少5年内，如果是可植入器械则至少15年内，保存如下文件供主管当局查阅：
— the declaration of conformity,	一符合性声明，
— the documentation referred to in the seventh indent of Section 3.1,	一第3.1点第4小项所述的文件，
— the changes referred to in Section 3.4,	一第3.4点所述的更改，
— the decisions and reports from the notified body as referred to in the final indent of Section 3.4 and in Sections 4.3 and 4.4,	一第3.4点最后一点和4.4点中所述的来自公告机构的决议和报告。
— where appropriate, the certificate of conformity referred to in Annex III.	一适当时，附录III所述的型式检验证书。
一适当时，附录III所述的型式检验证书。	
6. Application to devices in Class IIa	6．IIa类器械的应用
In line with Article 11(2), this Annex may apply to products in Class IIa, subject to the following:	依据第11条第（2）款的要求，本附录可以应用于IIa类产品，满足下列要求：
6.1. By way of derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII and meet the requirements of this Directive which apply to them.	

6.2. For devices in Class IIa the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3 of Annex VII for at least one representative sample for each device subcategory for compliance with the provisions of this Directive. 6.3. In choosing representative sample(s) 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 or biological properties) that have been carried out in accordance with this Directive. The notified body shall document and keep available to the competent authority its rationale for the sample(s) taken. 6.4. Further samples shall be assessed by the notified body as part of the surveillance assessment referred to in Section 4.3.	6.1. 排除第2、3.1及3.2 点的规定，制造商借符合性声明确保并宣称其属于IIa类的产品按照附录VII第3点所述的技术文件制造，并符合本指令对其适用的要求； 6.2. 对于IIa类器械，作为第3.3部分中的评估的一部分，公告机构应该对每一个同类器械组选取至少一个代表性样本，评估附录VII第3点中描述的技术文档，以判定对本指令规定的符合性。 6.3. 在选择代表性样本时，公告机构应考虑工艺的先进性、类似的设计、工艺、制造和灭菌方法、预期用途和任何先前的依据本指令而开展的相关评估（如，关于物理、化学或生物学特性的评估）。公告机构应向主管当局书面说明其所选择样本的理由。 6.4. 作为第4.3部分所述的监督评估的一部分，公告机构将评估额外的样本。
ANNEX VII **EC 符合性声明** 1. The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative who fulfils the obligations imposed by Section 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by Section 5 ensures and declares that the products concerned meet the provisions of this Directive which apply to them. 2. The manufacturer must prepare the technical documentation described in Section 3. The manufacturer or his authorised representative must make this documentation, including the declaration of conformity, available to the national authorities for inspection purposes for a period ending at least five years after the last product has been manufactured. In the case of implantable devices the period shall be at least 15 years after the last product has been manufactured. 3. The technical documentation must allow assessment of the conformity of the product with the requirements of the	**附录VII** **EC 符合性声明** 1. EC符合性声明是指履行第2点（以无菌状态上市的产品及具有量测功能的器械）及第5点规定的义务的制造商或其授权代表确保并声明其产品符合本指令适用规定的一种程序。 2. 制造商应准备一份如第3点所述的技术文档。制造商或其授权代表必须将此份技术文档连同其符合性声明，自该产品最后一批制造完成之日起保存至少5年，如果是可植入器械则至少15年，以供国家权责机构检查。 3. 技术文档必须能够评估产品对本指令规定的符合性，特别应包括下列各项：

Directive. It must include in particular: — a general description of the product, including any variants planned and its intended use(s), — design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc., — the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product, — the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full, — in the case of products placed on the market in a sterile condition, description of the methods used and the validation report, — the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer, — the solutions adopted as referred to in Annex I, Chapter I, Section 2, — the pre-clinical evaluation, — the clinical evaluation in accordance with Annex X, — the label and instructions for use. 4. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. He shall notify the competent authorities of the following incidents immediately on learning of them: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics on the performance of a device for the	—对产品的大体描述，包括任何计划中的改变及其预期用途， —设计图纸，预想的制造方法和组件图，零配件图，电路图，等等， —为使上述图形、图样及产品操作易于了解的解释及说明， —风险分析的结果和有关指令第5条所列标准全部或部分适用的清单，以及未全部采用第5条标准时，有关为符合指令基本要求所采取的解决方法的描述。 —以无菌状态上市的产品须叙述所使用的灭菌方法以及灭菌方法的确认报告， —已开展的设计计算及检验的结果等；如果器械须和其他器材连接以便依其预期目的运行，应证明器械在与具有制造商指定之特性的其他器材连接后仍符合基本要求， —所采取的如附录I第1章第2点所述的解决方法， —临床前评价， —附录X中所述的临床评价， —标签和使用说明书。 4．制造商应建立并系统化程序并随时予以更新，以评审器械的生产后相关经验，包括附录X中所述的规定并设法采取必须的矫正措施的承诺。本项承诺还须包括制造商在得知下列事件时立即通知主管当局的义务： （i）器械的特性和/或性能异常或损坏,以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的标识或使用说明。 （ii）与器械的特性及/或性能有关的技术上或医学上的原因，导致(i)项中所述的情形，致使制造商系统地召回同型号

reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer. 5. With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in _M5 Annex II, IV, V or VI _. Application of the abovementioned Annexes and the intervention by the notified body is limited to: — in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions, — in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements. Section 6.1. of this Annex is applicable. 6. Application to devices in Class IIa In line with Article 11 (2), this Annex may apply to products in Class IIa, subject to the following derogation: 6.1. where this Annex is applied in conjunction with the procedure referred to in Annex IV, V or VI, the declaration of conformity referred to in the abovementioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this Directive which apply to it.	的器械。 5．对于以无菌状态上市的产品和具有测量功能的I类器械，制造商不仅必须遵守本附录的规定，同时也必须遵守附录II、IV、V或VI所述的程序之一。前述附录的应用及公告机构的介入仅限于下列情况： —以无菌状态上市的产品，仅限于有关确保和维持产品无菌状态的制造部分， —具有测量功能的器械，仅限于有关使产品符合测量学要求的制造部分。 本附录第6.1 点亦适用。 6．IIa类产品的应用 依据第11条第（2）款的要求，本附录可以应用于IIa类产品，满足下列要求： 6.1．如果本附录配合附录IV、V或VI的程序应用时，前述附录中所述的符合性声明视为一个单独的声明。至于以本附录为基础的声明，制造商必须确保并声明其产品设计符合本指令中对其适用的规定。
ANNEX VIII **STATEMENT CONCERNING DEVICES FOR SPECIAL PURPOSES** 1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative_M5_____ _must draw up the statement containing the information stipulated in Section 2. 2. The statement must contain the following information: 2.1. for custom-made devices: — the name and address of the manufacturer, — data allowing identification of the device in question, — a statement that the device is intended for exclusive use by a particular patient, together with the name of the	**附录VIII** **有关特殊目的的器械的声明** 1．有关特别定制或设计为临床调查用的器械，制造商或其授权代表必须起草一份包含第2点所述资料的声明。 2．该声明必须保护如下信息： 2.1．对于定制器械： —制造商名称和地址， —能够识别该器械的数据， —该器械仅供某一特定患者使用的声明，连同患者的姓名，

patient, — the name of the medical practitioner or other authorized person who made out the prescription and, where applicable, the name of the clinic concerned, — the specific characteristics of the product as indicated by the prescription, — a statement that the device in question conforms to the essential requirements set out in Annex I and, where applicable, indicating which essential requirements have not been fully met, together with the grounds; 2.2. for devices intended for the clinical investigations covered by Annex X: — data allowing identification of the device in question, — the clinical investigation plan, — the investigator's brochure, — the confirmation of insurance of subjects, — the documents used to obtain informed consent, — a statement indicating whether or not the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, — a statement indicating whether or not the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, — the opinion of the ethics committee concerned and details of the aspects covered by its opinion, — the name of the medical practitioner or other authorized person and of the institution responsible for the investigations, — the place, starting date and scheduled duration for the investigations, — a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient. 3. The manufacturer must also undertake to keep available for the competent national authorities: 3.1. For custom-made devices, documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow	—开具处方的医疗从业人员或其他经授权人员的姓名，适当时，包括相关诊所的名称， —相关医疗处方中规定的器械特性， —器械符合附录I基本要求的声明以及，适当时标示出未完全满足的基本要求，并说明理由； 2.2．附录X所涵盖的临床调查用的器械： —能够识别该器械的资料， —临床调查计划， —调查者手册， —项目保险证明， —用于获取同意信息的文件， —表明该器械是否作为整体的一部分，与附录I第7.4点所述的某种物质或人血衍生物组合的声明， —表明该器械是否使用2003/32/EC指令中所述的动物源性组织制造而成的声明， —相关伦理委员会的意见以及这份意见所涵盖的各个方面的详细信息， —对该临床调查负责的医学从业人员或其他授权人员和机构的名称， —临床调查开展的地点，开始日期和计划的持续时间， —器械除了临床调查所涵盖的方面外还满足基本要求的声明，以及对于临床调查中的那些方面，已采取了所有的防范措施以保护患者的健康和安全的声明。 3．制造商应负责将下列资料提供国家主管当局参考： 3.1．对于定制器械，足以使该产品的设计、制造及功能得到了解的文件，其中应包括预订的功能，以便评估其是否

assessment of conformity with the requirements of this Directive. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph; 3.2. For devices intended for clinical investigations, the documentation must contain: — a general description of the product and its intended use, — design drawings, methods of manufacture envisaged, in particular as regards sterilisation, and diagrams of components, sub-assemblies, circuits, etc., — the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product, — the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive if the standards referred to in Article 5 have not been applied, — if the device incorporates, as an integral part, a substance or human blood derivative referred to in Section 7.4 of Annex I, the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device, — if the device is manufactured utilising tissues of animal origin as referred to in Directive 2003/32/EC, the risk management measures in this connection which have been applied to reduce the risk of infection, — the results of the design calculations, and of the inspections and technical tests carried out, etc. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation referred to in the first paragraph of this Section. The manufacturer must authorise the assessment, or audit where necessary, of the effectiveness of these measures. 4. The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years. 5. For custom-made devices, the manufacturer must undertake to review and document experience gained in the	符合本指令的规定。 制造商应采取所有必要的措施以确保制造过程制造出来的产品是依据第一段中提及的文件。 3.2．当器械用于临床调查时，文件也须包含： —产品的大体描述及其预期用途， —设计图纸、拟想的制造方法，尤其关于灭菌、组件图、零配件图、电路图等。 —理解上述的产品操作、图纸和图表所必要的描述和解释。 —风险分析的结果和第5条中提到的全部或部分采用的标准的清单，以及如果没有采用第5条中所述的标准，而为了符合本指令的基本要求所采取的解决方法的描述， —如果该器械作为整体的一部分，与附录I中第7.4点中所述的物质或人血衍生物组合，考虑到该器械的预期目的，为了评估该物质或人血衍生物的安全性、质量和有用性，对这种组合开展的测试的资料。 —如果该器械使用2003/32/EC指令中所述的动物源性组织制造而成，用来减少在这种组合的感染风险的风险管理措施， —设计计算结果、已开展的检查结果和技术测试结果等。 制造商必须采取所有必要的措施以确保制造过程所生产的产品是依据本条款第一段落所提及的文档制造的。 制造商必须授权评估，或必要时审核这些措施的有效性。 4．与本附录有关的声明中所包含的信息应被保留至少5年，如果是可植入器械，则最少保存15年。 5．制造商应建立并系统化程序并随时予以更新，以评审器械的生产后相关经验，包括附录X中所述的规定并设法采取

post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them and the relevant corrective actions: (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health; (ii) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.	必须的纠正措施的承诺。本项承诺还须包括制造商在得知下列事件时立即通知主管当局的义务： （i）器械的特性和/或性能异常或损坏,以及可能或已导致患者或使用者死亡或健康情形恶化的不充分的标识或使用说明。 （ii）与器械的特性及/或性能有关的技术上或医学上的原因，导致(i)项中所述的情形，致使制造商系统地召回同型号的器械。
ANNEX IX **CLASSIFICATION CRITERIA** **I. DEFINITIONS** 1. Definitions for the classification rules 1.1. *Duration* Transient Normally intended for continuous use for less than 60 minutes. Short term Normally intended for continuous use for not more than 30 days. Long term Normally intended for continuous use for more than 30 days. 1.2. *Invasive devices* Invas ive device A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body. Body orifice Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.	**附录IX** **分类标准** **I. 定义** 1．分类原则中使用的定义 1.1．持续时间 短暂 通常指连续使用不超过60分钟。 短期 通常指连续使用不超过30天。 长期 通常指连续使用30天以上。 1.2．侵入性器械 侵入性器械 器材部分或全部透过人体的开口或表面穿入人体者。 人体的开口 人体自然的开口，及眼球的外表，或任何永久性的人工开口，如气孔。 手术侵入性器械

Surgically invasive device An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices. Implantable device Any device which is intended: — to be totally introduced into the human body or, — to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. 1.3. *Reusable surgical instrument* Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out. 1.4. *Active medical device* Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. _M5 Stand alone software is considered to be an active medical device. _ 1.5. *Active therapeutical device* Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.	借手术帮助穿透体表进入人体的侵入性器械。 出于本指令的目的，对于不同于上述医疗器械，不通过确定的人体开口而进入人体的器械，应视其为手术侵入性器材。 可植入器械 任何器械如果预期： 一完全导入人体，或， 一通过外科介入，取代眼睛表面或上皮细胞表面，并预期在手术后停留在手术部位。 任何器械的一部分借手术置入人体，并预期留置人体至手术后三十日者，也视为可植入医疗器械。 1.3．可重复使用的外科器具 通过切割、钻孔、锯、刮擦、刮削、钳夹、收回、剪或类似程序用于外科手术用途的器具，并不与任何医疗器材相连接而且能够在执行适当的程序后再重复使用。 1.4．有源器械 依靠电能或任何动力能源而不是直接依靠人体或重力产生能源，通过转换这能量而运作的任何医疗器械。用于在有源医疗器械与病人之间传送能量、物质或其它要素而没有任何重大改变的医疗器械，则并不被视为有源医疗器械。独立软件应被视为有源器械。 1.5．有源治疗器械 任何有源医疗器械，不管是单独使用或与其它医疗器械组合使用，通过支持、改变、取代或恢复生物功能或结构，达到治疗或缓解疾病、创伤或残疾的目的。 1.6．诊断用有源器械

1.6. *Active device for diagnosis* Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.	任何有源医疗器械，不管是单独使用或与其它医疗器械组合使用，用于提供探测、诊断、监视或处理生理条件、健康状态、疾病或先天的畸形的信息。
1.7. *Central circulatory system* For the purposes of this Directive, 'central circulatory system' means the following vessels: arteriae pulmonales, aorta ascendens, arcus aorta, 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, vena cava inferior.	1.7．中央循环系统 对于本指令的目的，中央循环系统意指以下血管： 肺动脉，升主动脉，主动脉弓，主动脉下降至主动脉分叉，冠状动脉，颈总动脉，颈外动脉，颈内动脉，脑动脉，无名动脉（头臂干），心静脉，肺静脉，上腔静脉，下腔静脉。
1.8. *Central nervous system* For the purposes of this Directive, 'central nervous system' means brain, meninges and spinal cord.	1.8．中枢神经系统 对于本指令的目的，中枢神经系统意指大脑，脑膜，脊髓。
II. IMPLEMENTING RULES	**II．执行规则**
2. Implementing rules	2．执行规则
2.1. Application of the classification rules shall be governed by the intended purpose of the devices.	2.1．分类规则的运用应受制于器械的预期用途。
2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.	2.2．如果器械是与其它器械组合起来使用的，则分类规则应对每一器械分别运用。附件应从使用它们的器械上分离后根据它们自己的实际情况进行分类。
2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.	2.3．驱动器械或影响器械的使用的软件，自动归于相同等级。
2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.	2.4．对于不仅仅或不主要应用在人体特定部位的器械，应依其最具风险的用途加以分类。
2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.	2.5．当某一器械适用于多条分类规则时，应根据制造商宣称的功能应用最严格的分类规则，使其归入较高的类别。
2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means 'an uninterrupted actual use of the device for the intended purpose'. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.	2.6．在计算第I章中第1.1点所述的持续时间时，持续使用是指"出于预期目的对器械实际的不间断使用"。但是，如果器械使用的间断是为了立即替换相似器械或相同器械，这应该被视为该器械的持续使用。

III. CLASSIFICATION	III. 分类
1. Non-invasive devices	1. 非侵入式器械
1.1. *Rule 1*	1.1. 规则 1
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	除非适用于以下列出的其他规则，所有非侵入式器械都属I类。
1.2. *Rule 2*	1.2. 规则 2
All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: — if they may be connected to an active medical device in Class IIa or a higher class, — if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.	用于输送或贮藏血液，体液或组织，注射、给予或进人体用的液体或气体的非侵入式器械在下列情形下都属于IIa类： —可能与IIa类或更高类别的有源医疗器材连接者， —用于贮藏或输送血液或其他体液或贮藏器官、部分器官或身体组织者， 其余都属于I类。
1.3. *Rule 3*	1.3. 规则 3
All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.	用于改变血液，其他体液或其他欲注射于人体的液体的非侵入式器械都属于IIb类，但处理包括过滤、气体的离心或交换、加热处理者则属于IIa类。
1.4. *Rule 4*	1.4. 规则 4
All non-invasive devices which come into contact with injured skin: — are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, — are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, — are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.	与受伤皮肤接触的所有非侵入式器械： —如果作为机械屏障用于压迫或吸收渗出物者属于I类， —如果主要用于治疗损伤了真皮且只能通过二期愈合而治愈的伤口者属于IIb类， —其余都属于IIa类，包括控制伤口微环境的器械。
2. Invasive devices	2. 侵入式器械
2.1. *Rule 5*	2.1. 规则 5所有经由人体开口进入人体的侵入式器械，手术侵入式器械及不与有源医疗器械连接，或预期用于和I类
_M5 All invasive devices with respect to body orifices, other than surgically invasive devices and which are not	

intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: _ — are in Class I if they are intended for transient use, — are in 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 a nasal cavity, in which case they are in Class I, — are in 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 a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.	器械连接的器械除外： —短暂使用者属于I类， —短期使用者属IIa类，但用于口腔至咽喉，耳管至耳膜处或使用于鼻腔内的器械则属I类， —长期使用者属IIb类，但用于口腔至咽喉，耳管至耳膜处，或用于鼻腔内且不易被粘膜吸收的器械则属IIa类。 除了手术侵入式器械以外，所有经由人体开口进入人体且与IIa类或更高类有源医疗器械连接者，属于IIa类。
2.2. *Rule 6* All surgically invasive devices intended for transient use are in Class IIa unless they are: — intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, — reusable surgical instruments, in which case they are in Class I, — intended specifically for use in direct contact with the central nervous system, in which case they are in Class III, — intended to supply energy in the form of ionising radiation in which case they are in Class IIb, — intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb, — intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.	2.2．规则 6 所有短暂使用的手术侵入式器械都属于IIa类，但下列情况除外： —通过直接与心脏或中央循环系统接触以诊断、监测或纠正该部位缺陷者都属于III类， —可再使用的外科器具属I类， —特定预期直接与中枢神经系统接触的器械属于III类， —预期以离子辐射形式供给能源者属于IIb类， —预期完全被人体吸收或产生生物效应者属于IIb类， —预期利用输送系统控制药物，考虑其应用方式，如果该过程的完成以具有潜在损害的方式进行者属于IIb类。
2.3. *Rule 7* All surgically invasive devices intended for short-term use are in Class IIa unless they are intended: — either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, — or specifically for use in direct contact with the central nervous system, in which case they are in Class III, — or to supply energy in the form of ionizing radiation in which case they are in Class IIb,	2.3．规则 7 所有短期使用的手术侵入式器械都属于IIa 类，但下列情况除外： —通过直接与心脏或中央循环系统接触以诊断、监测或纠正该部位缺陷者，都属于III类， —与中枢神经系统直接接触使用者属于III类， —以离子辐射形式供给能量者属于IIb类，

— or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,	—欲完全被人体吸收或产生生物效应者属于III类，
— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.	—在体内经过化学变化（置于齿内的器械除外）或控制药物者属于IIb类。
2.4. *Rule 8*	2.4. 规则 8
All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:	所有可植入器械及长期使用的手术侵入式器械都属于IIb类，但下列情况除外：
— to be placed in the teeth, in which case they are in Class IIa,	—置于齿内者属于IIa类，
— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,	—与心脏，中央循环系统或中枢神经系统直接接触使用者属于III类，
— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,	—欲完全被人体吸收或产生生物效应者属于III类，
— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.	—在体内经过化学变化（置于齿内的器械除外）或控制药物者属于III类。
3. Additional rules applicable to active devices	3. 应用于有源器械的其他规则
3.1. *Rule 9*	3.1. 规则 9
All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from 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 in Class IIb.	预期用于控制或交换能量的有源治疗器械属于IIa类。如果其管理或从人体交换能量的方式具有潜在的损害，考虑到能量应用的性质、密度和位置，则该器械属于IIb类。
All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.	所有用于控制或监测有源治疗器械使用状况的有源器械都属于IIb类，或用于直接影响前述使用状况的有源器械都属于IIb类。
3.2. *Rule 10*	3.2. 规则 10
Active devices intended for diagnosis are in Class IIa:	用于诊断的有源器械属于IIa类：
— if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,	—如果该器械用于供应将被人体吸收的能量，在可见光谱范围内照亮患者身体用的器械不在此列，
— if they are intended to image *in vivo* distribution of radiopharmaceuticals,	—显示体内放射药剂分布的影像者，
— 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, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of	—直接诊断或监测生理过程者，但特别用于监测性命悠关

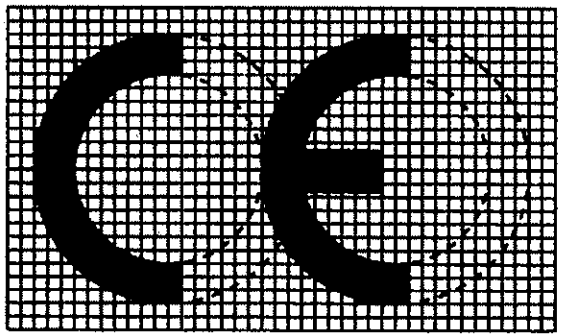
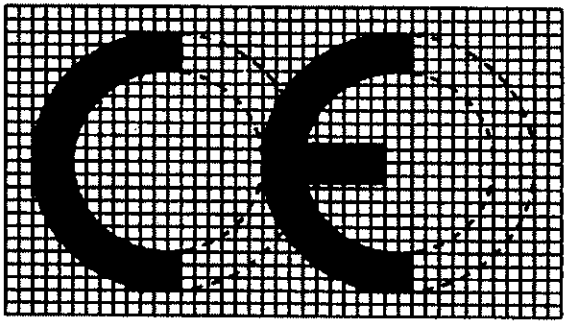
CNS in which case they are in Class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb. *Rule 11* All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in 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 in Class IIb. 3.3. *Rule 12* All other active devices are in Class I. 4. Special Rules 4.1. *Rule 13* All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive _M5 2001/83/EC _, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III. All devices incorporating, as an integral part, a human blood derivative are in Class III. 4.2. *Rule 14* All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III. 4.3. *Rule 15* All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb. All devices intended specifically to be used for disinfecting medical devices are in Class IIa. _M5 Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. _ This rule does not apply to products that are intended to clean medical devices other than contact lenses by means	的生理变化且此变化可能对患者导致立即危险者（如心功能，呼吸，中枢神经系统的变化）属第IIb类。 用于释放离子辐射及用于诊断和介入放射治疗的有源器械，包括控制或监视此类器械，或直接影响其功能的有源器械属于IIb类。 规则 11 所有用于控制和/或自体内取出（或放入体内）药物、体液或其他物质的有源器械属于IIa类，但下列情况除外： —考虑相关的物质本性、相关的身体部位及应用方式后有潜在损害者属于IIb类。 3.3. 规则 12 所有其他有源器械属于I类。 4. 特殊规则 4.1. 规则 13 作为整体的一个部分，与某种物质组合，该物质单独使用时符合2001/83/EC号指令的规定且可能对器械对人体产生作用起到辅助作用，这种器械属于III类。 所有器械，作为整体的一个部分，与人血衍生物组合使用，属于III类。 4.2. 规则 14 所有用于避孕或防止性病传染的器械都属于IIb类，但可植入器械或长期使用的侵入式器械则属于III类。 4.3. 规则 15 所有用于消毒，清洁，洗涤或适当时使隐形眼镜产生水合作用的器械都属于IIb类。 所有专门用于消毒医疗器械的器械都属于IIa类，如果专门

of physical action. 4.4. *Rule 16* _M5 Devices _ specifically intended for recording of X-ray diagnostic images are in Class IIa. 4.5. *Rule 17* All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only. 5. Rule 18 By derogation from other rules, blood bags are in Class IIb.	用于侵入式器械的消毒则属于IIb类。 本规则不适用于以物理方式清洁除隐形眼镜以外的其他医疗器械。 4.4. 规则 16 专门用于记录X光诊断影像的器械属于IIa类。 4.5. 规则 17 所有使用灭活的动物组织或其衍生物制造的器械属于III类，但此类器械若只与完整的皮肤接触则不在此列。 5. 规则 18 排除上述规则，所有血袋均属于IIb类。
ANNEX X **CLINICAL EVALUATION** 1. General provisions 1.1. As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data. The evaluation of this data, hereinafter referred to as 'clinical evaluation', where appropriate taking account of any relevant harmonised standards, must follow a defined and methodologically sound procedure based on: 1.1.1. Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where: — there is demonstration of equivalence of the device to the device to which the data relates, and — the data adequately demonstrate compliance with the relevant essential requirements. 1.1.2. Or a critical evaluation of the results of all clinical investigations made. 1.1.3. Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2. 1.1a In the case of implantable devices and devices in Class III clinical investigations shall be performed unless it is	**附录 X** **临床评价** 1. 一般规定 1.1. 一般地讲，对于器械在正常使用状况下符合附录I第1点及第3点所述的特性及功能要求的证明，以及对附录I第6点中所述的负作用和风险/受益比的可接受性的评估都应以临床资料为依据。对这些数据的评价，以下都称之为"临床评价"， 考虑到相关协调标准，适当时，必须符合以下列条件为基础的既定的合理的方法学程序： 1.1.1. 对当前有用的，与器械的安全性、性能、设计特点和预期用途有关的科学文献进行判断性评价，如果： 一能够表明器械与文献中的器械等同，和 一数据足以表明器械符合相关的基本要求。 1.1.2. 或者判断性评价所有已开展的临床调查的结果。 1.1.3. 或者判断性评价第1.1.1点和第1.1.2点中提供的组合的临床数据。

duly justified to rely on existing clinical data. 1.1b The clinical evaluation and its outcome shall be documented. This documentation shall be included and/or fully referenced in the technical documentation of the device. 1.1c The clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented. 1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated. 1.2. All the data must remain confidential, in accordance with the provisions of Article 20. 2. Clinical investigations 2.1. *Objectives* The objectives of clinical investigation are: — to verify that, under normal conditions of use, the performance of the devices conform to those referred to in Section 3 of Annex I, and — to determine any undesirable side-effects, under normal conditions of use, and assess whether they constitute risks when weighed against the intended performance of the device. 2.2. *Ethical considerations* _M5 Clinical investigations must be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the World Medical Assembly. _ It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. 2.3. *Methods*	1.1a 对于可植入器械和III类器械，必须开展临床调查，除非依靠现存的临床数据能够对其进行合理的证明。 1.1b 临床评价及其结果应形成文件。器械的技术文档应包括该文件或对其完全引用。 1.1c 应利用上市后监督获得的数据对临床评价及其文件进行积极更新。如果认为不需要将上市后临床随访作为上市后监督的一部分，必须给予合理的证明并形成文件。 1.1d 如果基于临床数据而对器械符合基本要求的证明被认为不适当，则对任何排除都必须以风险管理输出为基础，并考虑器械与人体相互作用的特点、预期的临床性能以及制造商的声明，然后给出充分的证明。可以通过性能评价、台案测试以及经充分证实的临床前评价而对器械满足基本要求的符合性给予足够的证明。 1.2．依据第20条的规定，所有的数据都必须保密。 2．临床调查 2.1．目标 临床调查的目标为： —证明器械在正常使用状况下，其功能符合附录I第3点的规定，及 —决定器械在正常使用状况下是否产生任何负面作用，并衡量器械设计的预期性能以评估这些副作用是否造成风险。 2.2．伦理考虑 临床调查的执行应符合1964年于芬兰赫尔辛基举行的第十八届世界医学大会通过的赫尔辛基宣言，以世界医学大会最新修订的版本为准。所有保护人类的方法必须遵守赫尔

2.3.1. Clinical investigations must 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 for the device; these investigations must include an adequate number of observations to guarantee the scientific validity of the conclusions. 2.3.2. The procedures used to perform the investigations must be appropriate to the device under examination. 2.3.3. Clinical investigations must be performed in circumstances similar to the normal conditions of use of the device. 2.3.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients must be examined. 2.3.5. All serious adverse events must be fully recorded and immediately notified to all competent authorities of the Member States in which the clinical investigation is being performed. 2.3.6. The investigations must be performed under the responsibility of a medical practitioner or another authorized qualified person in an appropriate environment. The medical practitioner or other authorized person must have access to the technical and clinical data regarding the device. 2.3.7. The written report, signed by the medical practitioner or other authorized person responsible, must contain a critical evaluation of all the data collected during the clinical investigation.	辛基宣言的精神，其中包括临床调查过程中的每一步，从最初的需求考虑和研究合理性的证实到临床结果的公布。 2.3．方法 2.3.1．临床调查必须建立在反映最新科技知识的适当的调查计划基础之上，它还可以被定义为确认或反驳生产厂商对于器械的声明；这些调查必须包括适当数量的观察资料，以保证调查结论的科学有效性。 2.3.2．临床调查所采用的程序必须适用于测试的器械。 2.3.2．临床调查必须在等同于器械正常使用的条件下开展。 2.3.4．器械所有适当的特征，包括器械的安全性和有效性以及对患者的影响都要进行检验。 2.3.5．对于所有严重的不良事件，必须作出完整记录并立即通知开展临床调查的成员国的主管当局。 2.3.6．临床调查必须在适当的环境中，由执业医生或经授权具备相关资格的人员负责进行。执业医生或经授权的负责人员必须有权力使用关于器械的技术资料及临床资料。 2.3.7．由执业医生或经授权的负责人员所签署的书面报告，必须包含对在临床调查中所收集的资料的判断性评价。
ANNEX XI **CRITERIA TO BE MET FOR THE DESIGNATION OF NOTIFIED BODIES** 1. The notified body, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be directly involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities. This in no way precludes the possibility of exchanges of technical information between the manufacturer and the body. 2. The notified body and its staff must carry out the assessment and verification operations with the highest degree	**附录XI** **认可公告机构准则** 1．公告机构的负责人及执行评估与确认的人员不得是受检器械的设计者、制造者、供应商、安装人员或使用者，亦不得为前述人员的授权代表。他们不得直接参与器材的设计、制造、行销或维修工作，亦不得担任参与前述工作的团体的代表。这决不会妨碍制造商与公告机构之间技术资讯的交流。

of professional integrity and the requisite competence in the field of medical devices and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of the verifications. Should the notified body subcontract specific tasks connected with the establishment and verification of the facts, it must first ensure that the subcontractor meets the provisions of the Directive and, in particular, of this Annex. The notified body shall keep at the disposal of the national authorities the relevant documents assessing the subcontractor's qualifications and the work carried out by the subcontractor under this Directive.	2．公告机构及其员工应以最高的职业道德及医疗器械领域所需要的能力执行评估及确认工作，并应拒绝一切压力和诱惑，特别是金钱上的诱惑及来自与检查结果有关的个人或团体的压力及引诱，以保持其判断及检查结果不受影响。公告机构如将与事实建立和确认的特定任务分包出去时，首先应确保分包机构符合指令及本附录的要求及规定。公告机构应将评估其分包机构的资格审查资料及受分包的业务资料提供其国家权责机构参考。
3. The notified body must be able to carry out all the tasks assigned to such bodies by one of Annexes II to VI and for which it has been notified, whether these tasks are carried out by the body itself or on its responsibility. In particular, it must have the necessary staff and possess the facilities needed to perform properly the technical and administrative tasks entailed in assessment and verification. _M1 This presupposes the availability of sufficient scientific staff within the organisation who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Directive and, in particular, those set out in Annex I. _ It must also have access to the equipment necessary for the verifications required.	3．公告机构应有能力执行或由其他机构代为执行附录II到附录VI所有经确定的且经过认可的工作。特别地，公告机构应具备所需的人员及设备，以便适当地执行与评估及确认有关的技术性及行政工作。鉴于本指令的要求，特别是附录I中的那些要求，组织应具备足够的科技人员，这些科技人员对于机构已经得到认可器械，要拥有丰富的评估知识和经验，以评估器械的医疗功能和性能。这些人员还必须有权力使用确认工作所需的设备。
4. The notified body must have: — sound vocational training covering all the assessment and verification operations for which the body has been designated, — satisfactory knowledge of the rules on the inspections which they carry out and adequate experience of such inspections, — the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.	4．公告机构必须： —对机构被指定的评估及确认工作进行全面的职业培训， —对所执行的检验规定有足够的知识及适当的经验， —具备拟定所需证书、记录及报告以表明检查已经实施的能力。
5. The impartiality of the notified body must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.	5．公告机构应保证其公正性，其人员的报酬不应决定于执行检查的次数及检查的结果。
6. The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.	6．公告机构必须承担民事责任保险，除非各成员国依其国家法律负担责任或成员国自己直接执行检查。
	7．依据本指令或使其生效的国家法律规定，公告机构的人

7. The staff of the notified body are bound to observe professional secrecy with regard to all information gained in the course of their duties (except *vis-à-vis* the competent administrative authorities of the State in which their activities are carried out) pursuant to this Directive or any provision of national law putting it into effect.	员必须对其在工作中取得的所有资料保守工作机密（对活动进行所在成员国的主管行政机构除外）。
ANNEX XII **CE MARKING OF CONFORMITY** The CE conformity marking shall consist of the initials 'CE' taking the following form:  — If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. — The various components of the CE marking must 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XII** **CE 符合性标识** CE符合标示应包含如下形式的大写"CE"字母:  —若要对标识进行缩小或放大，则必须是对上图等比例的缩小或放大。 —CE标识中两个字母的高度必须一致，不得低于5mm。小型器械可免于此最低尺度的限制。