MDR Annex Ⅰ 附录一
General safety and performance requirements Checklist
通用安全和性能要求检查表

General safety and performance requirements 通用安全和性能要求	Applicability 适用性	Standards Used 应用标准	Evidence compliance **or reason for no applicability** 符合性证据或不适用理由	Location -section 位置-章节
CHAPTER I GENERAL REQUIREMENTS 第1章 一般要求				
1.Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high. 1.器械应具备制造商预期的性能，并确保其设计和结构在正常使用条件下适用于其预期用途。器械应安全有效，且不得对患者的临床症状或安全或者使用者或其他人员（如适用）的安全和健康造成损害，在最大限度保护健康和安全的同时，器械使用的可接受风险与其对患者的受益相比，应在可接受范围内，并应考虑到符合现有认知水平。				
2.The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio. 2.本附录中尽可能降低风险的要求，指尽可能降低风险的同时不会对受益-风险比产生不利影响。				
3.Manufacturers shall establish, implement, document and maintain a risk management system.				

3. 制造商应建立、实施、记录和维护风险管理体系。 Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall: 风险管理应理解为在器械整个生命周期中为连续迭代过程，需定期进行系统更新。进行风险管理制造商应做到： (a) establish and document a risk management plan for each device; 制订并记录各器械的风险管理计划； (b)identify and analyse the known and foreseeable hazards associated with each device; 识别和分析与各器械相关的已知和可预见的危害； (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; 估计和评价在预期使用时及在可合理预见的使用不当时产生的相关风险； (d) eliminate or control the risks referred to in point (in accordance with the requirements of Section 4; 根据第 4 节的要求消除或控制(c)点所述的这些风险； (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and 评估生产阶段，特别是上市后监管体系的信息、危害及其发生频率、评估其相关风险及总体风险、风险利益比和风险可接受性。 (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section				

根据(e)点所述信息影响的评估，必要时根据第 4 节的要求修改控制措施。				
4.Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: 4.制造商就器械的设计和生产所采取的风险控制措施应符合安全原则，并考虑到现有的技术水平。为降低风险，制造商应对风险进行管理，使各危害相关的剩余风险及总剩余风险控制在可接受范围内。在选择最合适的解决方案时，制造商应依据下述优先级原则： (a) eliminate or reduce risks as far as possible through safe design and manufacture; 通过安全的设计和生产尽可能消除或降低风险； (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and 如适合，采取适当保护措施，关于无法消除的风险，包含必要时的报警；且 (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. 提供安全信息（警戒/预防措施/禁忌），并在适当情况下向使用者提供培训。 Manufacturers shall inform users of any residual risks. 制造商应将剩余风险告知使用者。				
5.In eliminating or reducing risks related to use error, the manufacturer shall: 5.在消除或减少使用不当相关风险时，制造商应： (a) reduce as far as possible the risks related to the ergonomic features				

of the device and the environment in which the device is intended to be used (design for patient safety), and 尽量降低因器械人体工程学特点及其预期使用环境所造成的风险(针对患者安全而设计)，以及 (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 针对技术知识、经验、教育、培训和使用环境，以及预期使用者医疗及身体条件（如适用）的注意事项（针对非专业、专业、残疾或其他使用者而设计）。				
6.The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions. 6.如器械在正常使用环境中使用并根据制造商的指示进行适当维护保养，在制造商声称的使用期限内器械的特性和性能不得对患者、使用者或其他人员(如适用)的健康或安全造成损害。				
7.Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. 7.器械的设计、生产和包装应确保在根据制造商提供的说明和信息进行运输和储存期间（如温度和湿度的波动），不会对器械在预期使用期间的特性和性能造成				

不利影响。				
8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. 8. 与正常使用条件下器械预期性能对患者和/或使用者产生的潜在益处相比，所有已知和可预见的风险及任何不良影响应最小化并控制在可接受范围内。				
9. For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. 9. 对于在附录十六中所列出的，制造商未声称用于医疗目的之器械，应充分了解在第 1 节和第 8 节规定的通用安全要求，即在预期条件下出于预期目的而使用器械时，器械不得出现任何风险，或出现不超过与产品使用相关的最大可接受风险，这符合高水平保障人员安全和健康原则一致。				
CHAPTER II REQUIREMENTS REGARDING DESIGN AND MANUFACTURE **第2章 设计和生产相关要求**				
10. Chemical, physical and biological properties 10. 化学、物理和生物学特性				
10. 1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: 器械的设计和生产应当能确保符合第 I 章中所述的特性和性能要求。特别注意： (a) the choice of materials and substances used, particularly as regards toxicity				

and, where relevant,flammability; 使用材料和物质的选择，特别是毒性和易燃性（如适用） (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution,metabolism and excretion;所使用材料和物质与生物组织，细胞及体液间的相容性，及考虑到器械使用目的及相关的吸收、分布、新陈代谢和排泄； (c) the compatibility between the different parts of a device which consists of more than one implantable part; 器械不同部件之间的兼容性，该器械由多个可植入部件组成； (d)the impact of processes on material properties;过程对材料性能的影响； (e)where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; 若适用，生物物理学或建模研究结果有效性已事先获得证实； (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength,ductility, fracture resistance, wear resistance and fatigue resistance; 所使用材料的机械性能，在适当情况下反映诸如强度、延展性、抗断裂性、耐磨性和耐疲劳强度等问题； (g) surface properties; and 表面活性； (h) the confirmation that the device meets any defined chemical and/or physical specifications.确认该器械满足任何确定的化学和/或物理要求。				
10. 2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and				

frequency of exposure. 器械的设计、生产和包装应尽可能降低污染物和残留物对患者造成的风险，同时考虑到器械预期用途以及参与器械运输、储存和使用的人员。 应当特别注意暴露于这些污染物和残留物的组织以及暴露时间与频率。				
10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use. 器械的设计和生产应以能使其可安全地与材料和物质（包括气体）一起使用，且在预期使用时，这些材料和物质会与器械接触；若器械预期用于管理医疗产品，根据管理这些医疗产品的条款和限制，则其设计和生产应使其能够与相关的医疗产品兼容，并应可根据其相应的指示和预期用途维护医疗产品和器械的性能。				
10.4. Substances 物质				
10.4.1.Design and manufacture of devices 器械的设计和生产				
substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. 器械的设计和生产应尽可能降低由物质或微粒（包括磨屑、降解产物和加工残留物）造成的风险，而此类物质或微粒可能由器械产生。 Devices, or those parts thereof or those materials used therein that: 器械或其部件或其使用的材料： — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or				

— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: - 具有侵入性，并与人体直接接触，或 -（重新）为人体输送药物、体液或其他物质（包括气体），或 运输或储存待（重新）为人体输送药物、体液或物质（包括气体），在根据第 10.4.2 节进行调整时，应仅包含浓度高于 0.1%重量比的以下物质： (a)substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or 1A 或 1B 类有致癌、致突变或生育毒性('CMR')的物质，依据欧洲议会和理事会第 1272/2008 号法规附录 VI 第 3 部分判断，或 (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in 有科学证据证明可能对人类健康造成严重影响的具有内分泌干扰性质的物质，根据欧洲议会和理事会第 1907/2006 号法规（[2]）第 59 条规定程序识别，或者委员会根据欧洲议会和理事会第 528/2012 号法规（[3]）第 5（3）条第一段通过授权法案后，根据本法规规定之与人类健康相关准则识别。				
10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances				

The justification for the presence of such substances shall be based upon: 10.4.2 关于存在 CMR 和/或内分泌干扰物的理由，存在此类物质的理由应基于： (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. (a)对潜在患者或使用者暴露于该物质下情况进行分析和判断； (b)对可能的替代物质、材料或设计进行的分析，（在可用时）包括有关独立研究、同等评审研究、相关科学委员会的科学意见等信息，以及对这些替代品可用性的分析； (c)论证可能的物质和/或材料替代品（如有）或设计变更（如可行）不适用于维护产品功能、性能和利益-风险比的原因；包括要考虑这些器械的预期用途是否包括儿童治疗，或孕妇或哺乳妇女治疗，或对其他特别容易受到此类物质和/或材料影响的患者群体的治疗； (d)如适用和可用时，基于根据第 10.4.3 节和 10.4.4.节制定的最新相关的科学委员会指南。				

10.4.3.Guidelines on phthalates 10.4.3 邻苯二甲酸酯使用指南 For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate 为达到本附录第 10.4 条 的目的，委员会应尽快并于 2018 年 5 月 26 日向相关科学委员会提供任务以制定指南，且本指南应在 2020 年 5 月 26 日前编制好。委员会的任务至少应包含对邻苯二甲酸酯存在的利益风险评价，其中邻苯二甲酸酯属于第 10.4.1 节要点（a）和（b）中所所述物质组中的任何一组。利益风险评价应考虑器械、可用替代物质和替代材料、设计和/或药物治疗使用的预期目的和环境。虽然根据最新科学证据认为是适当的，但应至少每五年更新一次本指南。				

(1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(2) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration,Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1).

(3) Regulation (EU) No 528/2012 of the European Parliament and the

（1）欧洲议会和理事会于 2008 年 12 月 16 日签发的关于物质和混合物分类、标签和包装的第 1272/2008 号法规，修订和废除第 67/548/EEC 号指令和第 1999/45/EC 号指令，并修订了第 1907/2006 号法规（OJ L 353，31.12.2008，p. 1）。

（2）欧洲议会和理事会于 2006 年 12 月 18 日签发的关于化学品注册、评价、授权和限制（REACH）的第 1907/2006 号法规（OJ L 396,30.12.2006，p. 1）。

（3）欧洲议会和理事会于 2012 年 5 月 22 日签发的关于在市场上提供和使用杀生物产品的第 528/2012 号法规（OJ L 167，27.06.2012,p. 1）。

10.4.4Guidelines on other CMR and endocrine-disrupting substances 其他CMR和内分泌干扰物质的指南 Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate. 随后，委员会应授权相关科学委员会按照第 107.4.3 中所述的要求，也为第 10.4.1 节要点（a）和（b）中所所述的其他物质制定指南。				
10.4.5 Labelling贴标 Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or,where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups 按照第 10.4.1 节所述的要求，若此中所使用的器械、其部件或材料，包含第 10.4.1 节中所述的浓度高于 0.1%重量比的物质，则应在器械本身和/或各单元的包装上或，（适当时）在销售包装上把此类物质清单标识清楚。若此类器械的预期用途，包括儿童治疗，或孕妇或哺乳妇女治疗，或对视为特别易受到此类物质和/或材料影响的其他患者群体的治疗，则关于这些患者群体的剩余风险、（如适用）预防措施信息，均应在使用说明中给出。				
10.5.Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.				

必须合理设计及生产器械，以尽量降低因物质意外进入器械而造成的风险，并且应考虑到器械及其预期使用环境的性质。				
10.6.Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials. 器械的设计和生产应尽可能减少与微粒尺寸和性能相关的风险，除非这些微粒接触到的是完好的皮肤，否则这些微粒会位于或可释放到患者或使用者体内。应特别注意纳米材料。				
11. Infection and microbial contamination **感染及微生物污染**				
11.1.Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids. 器械和生产过程的设计应尽可能消除或减少感染患者、使用者和（适用时）其他人的风险。设计应： (a) 尽可能减少并消除意外由于切割和刺破造成的风险，例如针刺损伤； (b) 使用便捷安全； (c) 尽可能降低器械的微生物泄漏和/或使用过程中的微生物暴露； (d) 防止器械或其所包含之物（例如样本或液体）受到微生物的污染。				

11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. 必要时，应将器械设计成便于进行安全清洁、消毒和/或再灭菌。				
11.3.Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer. 应对标记为具有特殊微生物种群的器械进行设计、生产和包装，以确保在投放到市场时，及在制造商规定的运输和储存条件下，器械依旧保持原样。				
11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user. 应根据适当流程，对在无菌状态下运输的器械进行设计、生产和包装，以确保在投放到市场时，及在制造商指定的运输和储存条件下，器械能保持无菌状态，除非旨在保持其无菌状态的包装遭到损坏，仍保持无菌，直至保护包装破损或出于使用目的而打开时。这些措施应确保最终使用者可清晰可见无菌包装的完整性。				
11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate,validated methods. 应通过适当的经过验证的处理、生产、包装和灭菌方法标识为无菌器械。				
11.6.Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. 用于灭菌的器械应采用适当且可控条件和设备进行生产和包装				
11.7. Packaging systems for non-sterile devices shall maintain the integrity and				

cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging 11.7 若器械在使用前灭菌，则非无菌器械的包装系统应保持产品的完整性和清洁度，以尽量减少微生物污染风险；此外，包装系统应适当考虑制造商指定的灭菌方法。				
11.8.The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile. 11.8 器械标识除带有灭菌产品的指示符号外，还应可区别市场上相同或相似器械的灭菌和非灭菌状态。				
12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body. 12 包含被认为是药品物质的器械，及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械。				
12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation. 12.1 对于第 1(8)条第一子段所指的器械，若单独使用，则该物质的质量、安全性和可用性将被视为是符合第 2001/83/EC 号指令第 1 条(2)点的医药产品，则应按照本法规中适用的符合性评价流程的规定，使用与第 2001/83/EC 号指令附录 I 所规定方法相似的方法进行验证。				
12.2.Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed				

by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution,metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential 12.2 预期植入到人体，以及由人体吸收或局部喷洒在人体上的物质或物质组合构成的器械，应遵从，（适用时）并受限于本法规与第 2001/83/EC 号指令附录 I 中规定的相关要求未涵盖方面，而这些相关要求用于按照本法规适用的符合性评价流程，对吸收、分配、新陈代谢、排泄、局部耐受性、毒性，与其他器械、医药产品呼呼其他物质和相互影响，及副作用的潜在影响进行评价。				
13.Devices incorporating materials of biological origin **13.含有生物来源材料的器械**				
13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: 13.1 对于使用由本法规涵盖的非活性或处理为非活性人源生物组织或细胞生产成的器械，根据第 1(6)条(g)点，适用以下规定： (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; 对用于器械生产的人源组织和细胞的捐赠、购买和测试应根据第 2004/23/EC 号指令完成。				

(b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular,safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;应对那些组织和细胞或其衍生物进行处理、保存和任何其他操作，从而为患者、使用者、（适用时）其他人员提供安全保障。特别是，应通过适当的来源方法，以及通过在生产过程中实施经验证的消除或灭活方法处理与病毒和传染因子安全性相关的问题。 (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC. 这些器械的可追溯体系应与第 2004/23/EC 号指令和第 2002/98/EC 号指令所规定可溯源性和数据保护要求是互补和相兼容				
13.2.For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives,shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral				

inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply. 13.2 对于使用非活性或处理非活性动物源组织或细胞，或其衍生物生产的器械，应适用以下规定： (a)在可行的情况下，考虑到动物种类，动物源组织和细胞或其衍生物应来自已经受兽医控制，即适合于组织预期使用的动物。由制造商保留动物地理来源信息。 (b)应获取动物源组织、细胞和物质或其衍生物，并对其进行处理、保存、测试和操作，从而为患者、使用者和其他人员（如适用）提供安全保障。特别是关于病毒和其他传播因子的安全性，应通过在生产过程中，实施经验证的消除或病毒灭活方法来解决，除非此类方法的使用会导致不可接受的降解，损害器械的临床益处。 (c)在使用动物来源的组织或细胞或其衍生物生产的器械，如第 722/2012 号法规所述，应适用该法规规定的特别要求。				
13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. 对于使用其他非活性生物物质生产的器械，在第13.1和13.2节所述的情况下，应				

对这些物质的进行加工、保存、测定和处理，以便为患者、使用者和其他人（如适用）提供安全性，包括整条废物处理链。特别是，应通过适当的来源方法，及通过在生产过程中实施经验证的消除或失活方法处理与病毒和传染因子安全性相关的问题。				
14. Construction of devices and interaction with their environment **14. 器械构造及其与环境之间的相互作用**				
14.1. If the device is intended for use in combination with other devices or equipment the whole combination,including the connection system shall be safe and shall not impair the specified performance of the devices.Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection. 若器械预定与其他器械或设备一起配合使用，必须保证整个系统（包括连接系统）具有安全性，同时不得改变本器械的指定性能。此类组合结构的任何使用限制应在标签和/或使用说明书上标明。应以尽量减少所有可能的风险（如误连接）的方式设计和构造使用者必须处理的连接件，例如流体、气体输送、电气或机械联轴节。				
14.2.Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;				

(c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; (e) the risks of accidental ingress of substances into the device; (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and (g) 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. 应采用适当方式设计和生产器械，确保尽可能地避免或减少以下内容： （a）与器械物理特征有关的伤害风险，包含体积/压力比、尺寸、和人体工程学特征（如适用）； (b)与可合理预见的外部影响或环境条件相关的风险，例如磁场、外部电场和电磁效应、静电放电、诊断或治疗过程的辐射、压力、湿度、温度、压力变化和压力加速或者无线电信号干扰； (c)与该器械使用相关的风险，当其接触材料、液体和物质时，包括其在正常使用条件下暴露接触的气体； (d)与软件和 IT 环境间的可能负相互作用相关的风险，器械在该 IT 环境内操作和相互作用； (e)物质意外进入器械的风险； (f) 在研究中正常使用或给予治疗期间，与其他器械相互干扰造成的风险； (g)由于下面原因导致的风险：材料老化、测试或控制机能精准度下降而无法维修或校正（如植入人体后）器械。				
14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.				

Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion. 必须适当地设计和生产器械，确保在正常使用期间和单一故障情形下尽量减少火灾或爆炸风险。应特别留意此类器械：其预期用途包括暴露于或与易燃易爆物质或可引燃物质结合使用的器械。				
14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. 器械的设计和生产应确保可安全且有效地进行调整、校准和维护。				
14.5.Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. 用于与其他器械或产品协同操作的器械设计和生产应确保其互通性和兼容性可靠且安全。				
14.6. Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used. 应根据人体工程学原理设计和生产任何测量、监测或显示器标度的器械，且考虑到器械的预期用途、使用者以及器械预期使用所在的环境条件。				
14.7.Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use. 14.7 应以此类方式设计和生产器械，以便于使用者、患者或其他人安全处置器械和/或相关废物。为此，制造商应研究并测试程序和措施，以便器械使用后可安全处置。这些程序应在使用说明中给出。				

15.Devices with a diagnostic or measuring function具有诊断或测定功能的器械				
15.1.Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer. 15.1 应以此类方式设计和生产具有测定功能的诊断器械和器械，应根据适当的科学和技术方法为其预期用途提供足够的准确度、精度和稳定性。准确度范围应由制造商指定。				
15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1). 15.2 具有监测功能的器械进行并且以合法单位表示的测量应符合理事会第 80/181/EEC 号指令关于成员国对于测量单位的相似法律以及废除第 71/354/EEC 号指令（[1]）的规定。				
(1) Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40). （[1]）1979 年 12 月 20 日关于成员国关于衡量单位法律的理事会第 80/181/EEC 号指令，并废除第 71/354/EEC 号指令。(OJ L 39, 15.2.1980, p. 40)				
16. Protection against radiation **16. 辐射防护**				
16.1. General 16.1 概述 (a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. (a) 必须适当地设计、生产和包装器械，确保在预定用途下尽量减少对患者、使				

用者和其他人员造成辐射，但在治疗和诊断目的使用下不对规定合理的剂量进行限制。 (b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified. (b) 发出有害或潜在危险辐射的器械的操作说明应包含关于发射辐射性质、保护患者和使用者的方法，以及避免误用和尽可能和适当减少安装固有风险的详细信息。此外，还应指定有关验收试验、性能试验、验收标准以及维修保养程序的信息。				
16.2. Intended radiation 16.2 预期辐射 (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. (a) 若器械因实现特定医疗目的而不可避免地辐射危害或潜在危害水平的电离和/或非电离辐射，并且其受益一般视为超过该辐射内固有的风险，则使用者必须可控制辐射。此类器械的设计和生产应确保相关可变参数在可接受公差范围内的再现性。 (b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with				

visual displays and/or audible warnings of such emissions. (b) 当器械用于发射有害或潜在危险的电离和/或非电离辐射时，应尽可能安装此类发射的可视显示器和/或声响报警信号。				
16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected. 16.3 应采用适当方式设计和生产器械，确保尽可能降低患者、使用者和其他人员遭受非预期、漫辐射或散射辐射暴露。在可能和适当的情况下，应选择减少患者、使用者和可能受影响的其他人的辐射暴露方法。				
16.4. Ionising radiation 16.4. 电离辐射 (a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. 旨在发射电离辐射的器械的设计和生产应考虑到第2013/59/Euratom号指令的要求，其中规定了防止由于暴露于电离辐射而产生危险的基本安全标准。 (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. 旨在发射电离辐射的器械的设计和生产应确保（如可能）考虑到可在治疗期间改变和控制和（如可能）监测所发射辐射的预期用途、数量、几何形状和质量。 (b) Devices emitting ionising radiation intended for diagnostic radiology shall be				

designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. 若会发射离子辐射的器械预定用于放射医学诊断，则应采用适当方式设计和生产器械，确保获得符合预期医疗用途的合适图像和/或输出质量，同时尽量减少对患者和使用者的辐射。 (d) Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation. 若会发射离子并预定用于放射医治的器械，则应采用适当方式设计和生产器械，确保可监控和控制器械辐射剂量、光束类型和能量以及辐射质量（如适用）。				
17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves17. 可编程电子系统——包含可编程电子系统的器械与本身就是器械的软件.				
17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use.In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far aspossible consequent risks or impairment of performance. 17.1 包含可编程电子系统（包括软件）的器械或者自身为器械的软件，其设计应根据其预期用途确保相应可重复性、可靠性和性能。在单一故障条件下，应采取适当手段以尽可能消除或降低由此造成的风险或性能损害。				
For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life				

cycle, risk management, including information security, verification and validation. 17.2 针对包含软件的器械或自身为器械的软件，应根据现有技术开发和生产软件，同时考虑开发生命周期原则、风险管理，包括信息安全、验证和确认。				
17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise). 17.3本节所指软件用于与移动计算平台结合使用，其设计和制作应考虑移动平台的具体特征（如，屏幕的大小和对比度）以及与其用途相关的外部因素（环境变化，如光照或噪声水平）。				
17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. 17.4 制造商应规定有关硬件、IT 网络特性和 IT 安全措施的最低要求，包括防止非授权访问、按预期运行软件的必要条件。	NA			
18. Active devices and devices connected to them 有源医疗器械				
18.1. For non-implantable active devices, in the event of a single 18.1 对于非植入式有源器械，在出现单一故障情况时，应采取适当的措施尽可能消除或减少由此产生的风险。	NA			
18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	NA			

18.2 当患者的安全性取决于内部电源时，此类器械应配备可确定电源状态的手段，并且当电源容量处于临界值时。必要时应在电源容量变为临界值之前，提供适当警告或指示。				
18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. 18.3若患者安全取决于外部供电，器械必须包含一个报警系统，用于指示任何电力故障。	NA			
18.4. Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. 18.4 若器械预定用于监测患者内一个或多个临床参数，器械必须配备适当报警系统，用于提供有关可导致患者死亡或健康状态严重恶化的警戒信息给使用者。	NA			
18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. 18.5 器械的设计和生产应尽可能降低产生电磁干扰的风险，以免影响相关器械或该使用环境下其他器械或设备的操作。	NA			
18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended. 18.6 器械的设计和生产应提供充足的抗电磁干扰天然免疫水平，使其足以使器械按预期操作。	NA			
18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as	NA			

indicated by the manufacturer. 器械的设计和生产应尽可能避免在正常使用器械期间和在单一故障情况下对患者、使用者或任何其他人造成意外电击危险，但前提是器械须按照制造商的指示安装和维护保养。				
18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorized access that could hamper the device from functioning as intended. 18.8 器械的设计和生产应尽可能保护对器械的未经授权访问，以免器械无法正常运行。	NA			
19. Particular requirements for active implantable devices 有源可植入器械的特殊要求				
19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or highfrequency surgical equipment, and (c) risks which may arise where maintenance and calibration are impossible, including: — excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism. 应采用适当方式设计和生产有源可植入器械，确保尽可能地避免或减少： (a) 根据特定参考文献，与使用能源相关的风险，如使用电力，器械的绝缘、漏泄电流和过热风险，	NA			

(b) 与医疗有关的风险，特别是使用除颤器或高频外科手术器械产生的风险， (c) 在不可能进行维护和校准时可能出现的风险，包括： - 漏泄电流过度增大； - 所使用材料的老化； - 器械产生的过热。 测量或控制机制准确性降低。				
19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure — if applicable, the compatibility of the devices with the substances they are intended to administer, and — the reliability of the source of energy. 有源可植入器械的设计和生产应确保 - 如适当，器械与其预期施用物质的兼容性， - 能源的可靠性。	NA			
19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts. 有源可植入器械（如适当）及其组成部分应可识别，以便允许在发现与器械或其组成部分相关的潜在风险之后采取任何必要的措施。	NA			
19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation. 有源可植入器械应附带可明确识别自身及其制造商的代码（特别是关于器械的类型和生产年份）；若必要，应可读取该代码，而不需要进行外科手术。	NA			
20. Protection against mechanical and thermal risks				

机械和热风险防护				
20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts. 20.1应采用适当方式设计和生产器械，确保防止患者和使用者遭受与机械特征有关的机械风险，例如：运动阻力、稳定性或运动部件等。				
20.2. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. 20.2 应采用适当方式设计和生产器械，确保尽量降低因器械振动引起的风险水平，并考虑利用先进技术和手段限制振动（尤其振动源处），除非振动是规定性能中一部分。				
20.3. Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise,particularly at source, unless the noise emitted is part of the specified performance. 20.3 应采用适当方式设计和生产器械，确保尽量降低因噪音释放而产生的风险水平，并考虑利用先进技术和手段减少噪音（尤其噪音源处），除非这种噪音是规定性能中组成部分。				
20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks. 20.4若使用者或他人必须操作连接到电力、气体、液压或气动能量供给源的端子和连接器，应采用适当方式设计和构造此类端子和连接器，确保尽量降低任何潜在风险。				

20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk. 20.5 当安装或重装某些部件时可能出现的失误将有可能成为风险的源头，此类部件的设计和构造应完全避免该风险，若无法实现，则应通过在部件和/或其外壳的信息说明。 20.5 当需要知道移动方向以避免风险，相同信息应在活动部件和/或其外壳说明。				
20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use. 20.6 在正常使用条件下，器械内可接触部件（不包括拟供热或达到给定温度的部件或区域）及其周围可触及部件不会达到造成危险的温度。				
21. Protection against the risks posed to the patient or user by devices supplying energy or substances 21. 通过器械供应能量或物质防止对患者或使用者造成危险				
21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user. 21.1 若器械预定用于为患者供给能量或物质，应采用适当方式设计和生产器械，确保能够准确地设置和维持输送量，从而足以保证患者和使用者的安全。				
21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far				

as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source. 21.2 器械应配备防止和/或指示输送可能产生危险的能量或物质数量方面的任何不足。器械必须集成适当手段，确保尽可能地防止危险等级的能源或物质从能源及/或物质来源中泄漏。				
21.3. The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient. 21.3 控制器和指示器功能必须明确地注明在器械上。若器械提供使用说明或者通过一个可视系统指示操作或调整参数，必须保证使用者和患者（如适用）易于理解这些信息。				
22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons 22. 防止制造商预期用于非专业人员使用的医疗器械所造成的危险				
22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply. 22.1由非专业人员使用的器械的设计和生产应使其适用于预期用途，其中考虑到可用于专业人员的技能和方法以及在非专业人员的技术和环境中合理预期差异导致的影响。制造商提供的信息和说明应易于非专业人员理解和应用。				
22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to: — ensure that the device can be used safely and accurately by the intended user at all				

stages of the procedure, if necessary after appropriate training and/or information, — reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results. 22.2 由非专业人员使用的器械的设计和生产应： -确保目标使用者在适当训练和/或信息获得后的所有必要治疗阶段均可安全且准确使用器械；和 -尽可能减少并消除意外由于切割和刺破造成的风险，例如针刺损伤；和 -尽可能减少预期使用者在处理器械以及（如适当）在结果解读中的错误风险。				
22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: — can verify that, at the time of use, the device will perform as intended by the manufacturer, and — if applicable, is warned if the device has failed to provide a valid result. 22.3 由非专业人员使用的器械（如适当）应包括非专业人员使用的规程 - 在使用时，可验证器械将按照制造商的意图工作，并且 - 如适当，若器械未能提供有效的结果，则发出警告。				
CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE **第III章 有关器械随附信息的要求**				
23. Label and instructions for use 23. **标签和使用说明书**				

23.1. General requirements regarding the information supplied by the manufacturer **23.1 制造商需提供的信息的一般要求** Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: 各器械应附有识别器械及其制造商所需的信息，并酌情将安全与性能信息传达给使用者或其他人。此类信息可能出现在器械本身、包装上或使用说明书中，若制造商有网站，则应在网站上提供并保持更新最新信息，同时考虑到以下因素： (a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience,education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. 标签和使用说明的介质、格式、内容、易读性和位置应适合于特定器械、其预期目的和对预期使用者的技术知识、经验、教育或培训。尤其是，使用说明书应以预期使用者容易理解的语言撰写，并且在适当时，补充图纸和图表。				
(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. 标签上所需的信息应在器械本身上提供。若不可行或不适当，则某些或所有信息可显示在各单元的包装上和/或多个器械的包装上。				

在向单个使用者和/或位置提供多个器械的情况下，若购买者如此同意，则可提供使用说明的单个副本，在任何情况下购买者可请求免费提供进一步的副本。				
(c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes. 标签应以人类可读的格式提供，并可通过机器可读信息，例如射频识别（"RFID"）或条形码来补充。				
(d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section. 使用说明应与器械一起提供。例外情形：对于Ⅰ类和Ⅱa类器械，若在无使用说明书的情形下同样可安全地使用器械，则无需此类使用说明书。除非本节其他地方另有规定。				
(e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge. 当向单个使用者和/或位置提供多个器械时，若购买者同意，则可提供使用说明的单个副本，但购买者在任何情况下可请求免费提供其他副本。				
(f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation. 若根据第207/2012号法规或根据本法规通过的任何后续实施规则中规定的条件，可向使用者提供非纸质格式（例如，电子格式）使用说明。				

(g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer. 需要传达给使用者和/或其他人的剩余风险应包括作为制造商所提供信息中的限制、禁忌症、预防措施或警戒。				
(h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall bedescribed in the documentation supplied with the device. 如适当，制造商提供的信息应采用国际公认的符号形式。使用的任何符号或识别颜色应符合协调标准或CS。若未协调标准或CS，符号和颜色应说明在随同器械提供的文件中。				
23.2. Information on the label**标签上的信息** The label shall bear all of the following particulars: 标签必须注明下面全部事项： (a) the name or trade name of the device; 器械的名称或商品名称；				
(b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; 使用者识别器械所必需的详细信息、包装内容以及对于使用者不明显的器械预期用途；				
(c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; 制造商的名称、注册商号或注册商标及其注册营业地点的地址；				

(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative; 授权代表的姓名和授权代表的注册营业地点地址（若制造商在欧盟以外有其注册营业地点）；				
(e) where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; 如适当，器械包含或采用的指示信息， - 药物，包括人血或血浆衍生物或 - 人源的组织或细胞或其衍生物或 - 动物源的组织或细胞或其衍生物，如第 722/2012 号法规所述。				
(f) where applicable, information labelled in accordance with Section 10.4.5.; 如适当，标签信息应符合第10.4.5节规定；				
(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; 器械的批号或序列号前面带有批号或序列号的词语或等同的符号（若适用）；				
(i) the UDI carrier referred to in Article 27(4) and Part C of Annex VII; 根据第 27(4)条和附录ⅤⅡ第 C 部分的 UDI；				
(i) an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; 明确表示可安全使用或植入器械的时间限制，至少表示为与之相关的年份和月份；				

(j)where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; 若没有表示可安全使用的日期，则标识生产日期。若日期清晰可辨，生产日期可作为批号或序列号的一部分；				
(k)an indication of any special storage and/or handling condition that applies; 指明适用的任何特殊储存和/或处理条件；				
(l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method; 若以无菌方式提供的器械，还应标识其无菌状态和灭菌方法；				
(m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users; 需要立即引起器械使用者和任何其他人的注意、需要采取的警戒或预防措施。该信息可保持最小量，在这种情况下，更详细的信息将出现在使用说明中，同时考虑到预期使用者；				
(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; 若器械用于一次性使用，则相应表示。制造商的一次性使用指示应在整个欧盟内保持一致；				
(o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; 若器械是已进行再处理的一次性使用器械，提供该事实的指示信息、已执行的再处理循环次数以及关于再处理循环次数的任何限制；				

(p) if the device is custom-made, the words ‘custom-made device’; 若器械是定制的，则提供词语“定制器械”；				
(q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation’; 一项表示信息，用于标识器械为医疗器械。若本器械仅预定用于临床研究，应标明“临床研究专用”；				
(r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; 若器械包含预计经由身体孔口引入人体或施加在皮肤上，并被人体吸收或局部喷洒在人体上的物质或物质组合，则提供器械的整体定量成分和负责实现主要预期作用的主要成分的定量信息；				
(s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.对于有源可植入器械，提供序列号，对于其他可植入器械，提供序列号或批号。				
23.3. Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’) 23.3 关于保持器械无菌条件的包装信息（“无菌包装”）： The following particulars shall appear on the sterile packaging: 无菌包装上应出现以下细节： (a) an indication permitting the sterile packaging to be recognised as such, 指明无菌包装标识； (b) a declaration that the device is in a sterile condition,				

声明该器械处于无菌状态； (c) the method of sterilisation, 灭菌方法； (d) the name and address of the manufacturer, 制造商名称和地址； (e) a description of the device, 器械说明； (f) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations, 若本器械仅预定用于临床研究，应标明“临床研究专用” (g) if the device is custom-made, the words ‘custom-made device’, 若属于定制器械，应标明“定制器械”； (h) the month and year of manufacture, 生产年月； (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and 安全使用或植入器械的时间限制的明确指示信息，并表示为与之相关的年月； (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before us 检查使用说明的说明，即若无菌包装损坏或在使用前不小心打开，该如何处理。				
23.4. Information in the instructions for use 23.4.使用说明书中的信息 The instructions for use shall contain all of the following particulars: 使用说明应包含以下全部详细规定： (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; 第 23.2 条（a）、（c）、（e）、（f）、（k）、（l）、（n）和（r）点所述的详细规定；				

(b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; 器械的预期用途具有适应症、禁忌症、患者目标群体和预期使用者（如适用）的明确规范；				
(c) where applicable, a specification of the clinical benefits to be expected. 如适用，提供预期的临床受益规范； (d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; 如适用，提供按照第32条的安全和临床性能总结链接； (e) the performance characteristics of the device; 器械的性能特征； (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; 如适用，提供信息用于医疗保健专业人员验证器械是否合适，并选择相应的软件和附录； (g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; 任何剩余风险、禁忌症和任何不良副作用，包括传达给患者的关于这方面的信 (h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it; 规范使用者适当地使用器械的要求，例如，若器械具有测定功能，提供其所要求的准确度； (i) details of any preparatory treatment or handling of the device before it is ready for use or during its use,such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all				

available methods for achieving those levels of disinfection; 在准备使用之前或在其使用（例如，灭菌、最终组装、校准等）期间器械的任何预处理或处理的细节，包括确保患者安全所需的消毒水平和实现那些消毒水平所需的所有可用方法； (j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; 所有特殊设备的任何要求或特殊培训或器械使用者和/或其他人的特定资格； (k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: 验证器械是否正确安装并是否准备好安全以及按制造商意图执行的信息（若相关）： — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, —预防和定期维护以及任何预备清洁或消毒的性质和频率的详细信息； — identification of any consumable components and how to replace them, —任何消耗部件的标识和更换方法； — information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and —任何必要的校准信息，其用以确保器械在其预期寿命期间正常和安全地工作； — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; —消除参与安装、校准或维修器械的人所遇到风险的方法。 (l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; 若提供的器械是无菌的，则无菌包装在使用前被损坏或无意打开的情况下，应提				

供说明。 (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; 若提供的器械是非无菌的，并且需要在使用前进行灭菌，应提供适当的灭菌说明。 (n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning,disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses; 若器械可重复使用，提供重复必需的适当处理过程的相关信息，包括清洁、消毒、包装以及（如适当）经过验证的适用于器械投放市场所在成员国的重新灭菌方法。应提供信息以识别该器械何时不得再使用，例如，材料老化迹象或允许重复使用的最大数量。 (n) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; 必要的指示信息，指示只有在制造商负责进行重新调整后符合基本安全和性能要求，方可重复使用该器械。 (o) if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation,where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;				

若器械带有一次性使用标识，在重复使用器械的情形下，制造商已知的特性和技术因素相关信息可能会构成风险。此信息应基于制造商风险管理文档的特定部分，应详细说明这些特征和技术因素。若按照第 23.1 节(d)点无需任何使用说明，该信息必须按要求提供给使用者。 (q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment; 对于旨在与其他器械和/或通用设备一起使用的器械： —信息用于识别这些器械或设备，以便获得安全组合，和/或 —有关器械和设备组合的任何已知限制的信息。 (r) if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device; 若器械发出辐射用于医疗用途： -关于发出辐射的性质、类型和（如适当）强度和分布的详细信息； -防止患者、使用者或其他人在使用器械期间受到意外辐射的方法。 (s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications,measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications,measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:				

有关允许向使用者和/或患者通知任何警示、预防措施、禁忌症、待采取措施以及与器械有关的使用限制信息。在相关情况下，此信息应允许使用者向患者简述所有警示、预防措施、禁忌症、待采取措施以及与器械有关的使用限制。该信息应酌情包括： — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, —器械发生故障或可能会影响安全的性能变化时的警示、预防措施和/或待采取措施； — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures,pressure, humidity, or temperature, - 警示、预防措施和/或就暴露于合理可预见的外部影响或环境条件采取的措施（例如磁场、外部电和电磁效应、静电放电、与诊断或治疗过程相关的辐射、压力、湿度、或温度； — warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, - 在特定诊断研究、评价或治疗处理或其他程序（例如，由影响其他设备的器械所发出的电磁干扰）期间，器械的合理可预见存在所造成的干扰风险的警戒、预防措施和/或待采取措施； — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances,				

any limitations or incompatibility in the choice of substances to be delivered, - 若器械用于管理人或动物源的生物物质药品、组织或细胞或其衍生物，则在选择交付物质时需考虑任何可能的限制或不相容性； — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and - 结合到器械中作为器械组成部分的药物或生物材料相关的警戒、预防措施和/或限制； — precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; - 与纳入器械的 CMR 或具有内分泌干扰性质或可能导致患者或使用者的致敏或过敏反应的材料相关的预防措施； (t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body,warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications,undesirable side-effects and risks relating to overdose; 若拟引入人体并由人体吸收或局部扩散在人体内的物质或物质组合构成，则该器械及其代谢产物产品与其他器械、药品和其他物质间相互作用的一般概况以及禁忌、不良副作用和过量风险的警戒和预防措施（如适用）。 (u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;				

对于可植入器械，有关患者可暴露材料和物质的总体定性和定量信息。 (v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: 为便于安全处理器械、其附录和与其一起使用的耗材（如有），应采取的警戒或预防措施。该信息应酌情包括： — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and —感染或微生物危害（例如，被人源潜在感染性物质污染的外植体、针或手术器械）； — physical hazards such as from sharps. -物理性危害（例如来自尖锐物）。 If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request; 若可按照第 23.1 节（d）点要求无使用说明，则应根据要求将这些信息提供给使用者； (w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; 对于非专业人员使用的器械，使用者应咨询医护专业人员。 (x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device; 对于根据本法规第1(2)条涵盖的器械，关于缺乏临床受益以及与器械使用相关的风险信息； (y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;				

使用说明书的发布日期，若已修订，最新版本使用说明书的发布日期和标识符号；。 (z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; 向使用者和/或患者发出关于与器械有关的任何严重事件的通知，应报告给使用者和/或患者所在成员国的制造商和主管机构。 (aa) information to be supplied to the patient with an implanted device in accordance with Article 18; 根据第 18 条向患者提供有关植入器械的信息。 (ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. 对于结合可编程电子系统的器械，包括软件或器械本身是软件，有关硬件、IT网络特性和IT安全措施的最低要求（包括防止未经授权的访问）对于运行软件来说所必要的。				