## REGULATION (EU) 2017/745

## Product Description

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| *Product Contains:*  🞎 Medicinal  *{填写申报产品名称}*  🞏 HSA  🞏 Animal tissue  🞏 Latex |
| *Product class according to Medical Devices Directive*  *{填写申报产品分类依据} (参考示例：Class I）* |
| Model/type  *{填写申报产品型号}* |
| Product Description including intended use  *{对产品进行描述 } 【可从产品结构、组成等方面进行描述】* |

**Manufacturer**

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| *Company：* *{填写制造商的企业名称 } （参考示例：Shenzhen Hlongmed Biotech Co.,Ltd.）* |
| *Address:* *{填写制造商的地址}* |
| *Postal address：{填写制造商的通讯地址}* |

### Conformity Assessment Procedure according to the following Annex of the Directive (pls. tick):

### Declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19(MDR regulation EU 2017/745) after drawing up the technical documentation set out in Annexes II and III.

### Signature

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| *The manufacturer confirms that all information given in the checklist is correct.* | | |
| Place and date：*{填写日期 }* | For the Manufacturer | Signature*{签名 }* |

### Version log

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| *This checklist has been updated to cater for changes made in the product, after initial compliance analysis, as follows:* | | |
| Product revision number/ID | Description of key changes  (Corresponding changes in compliance analysis overleaf , to be marked yellow.) | Place, date and signature |
| *{填写版本号 }* | *{对版本的主要变化进行描述}* | *{签字签日期 }* |
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| Clause | Description | Applicable or not? | Standard/Sub-clause(s) | Report/Document | Comments |
| --- | --- | --- | --- | --- | --- |
| I | ***General requirements*** |  |  |  |  |
| 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 level of protection of health and safety, taking into account the generally acknowledged state of the art. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 3. | Manufacturers shall establish, implement, document and  maintain a risk management system. 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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | establish and document a risk management plan for each  device; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (b) | identify and analyse the known and foreseeable hazards  associated with each device; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | estimate and evaluate the risks associated with, and occurring  during, the intended use and during reasonably foreseeable  misuse; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | eliminate or control the risks referred to in point (c) in  accordance with the requirements of Section 4; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 4. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | eliminate or reduce risks as far as possible through safe design  and manufacture; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (b) | where appropriate, take adequate protection measures,  including alarms if necessary, in relation to risks that cannot be  eliminated; and | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | provide information for safety  (warnings/precautions/contra-indications)  and, where appropriate, training to users.  Manufacturers shall inform users of any residual risks. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 5. | In eliminating or reducing risks related to use error, the  manufacturer shall: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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). | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 10. | Chemical, physical and biological properties | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | the choice of materials and substances used, particularly as  regards toxicity and, where relevant, flammability; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | the compatibility between the different parts of a device  which consists of more than one implantable part; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | the impact of processes on material properties; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (e) | where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |

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| (f) | the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength,  ductility, fracture resistance, wear resistance and fatigue resistance; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (g) | surface properties; and | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (h) | the confirmation that the device meets any defined chemical and/or physical specifications. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 10.4.  10.4.1 | Substances  Design and manufacture of devices  Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by  substances or particles, including wear debris, degradation products and processing residues, that may be  released from the device.  Devices, or those parts thereof or those materials used therein that:  — 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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 accordance with the  criteria that are relevant to human health amongst the criteria established therein. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | an analysis and estimation of potential patient or user exposure to the substance; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | where applicable and available, the latest relevant scientific committee guidelines in accordance with  Sections 10.4.3. and 10.4.4. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 10.4.3. | Guidelines on phthalates  For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the  relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The  mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates  which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The  benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as  well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 10.4.4. | Guidelines on other CMR and endocrine-disrupting substances  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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 10.4.5. | Labelling  Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances  referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the  presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or,  where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices  includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient  groups considered particularly vulnerable to such substances and/or materials, information on residual risks for  those patient groups and, if applicable, on appropriate precautionary measures shall be given in the  instructions for use. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 11.  11.1. | Infection and microbial contamination  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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick  injuries, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (b) | allow easy and safe handling, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 11.2. | Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 11.5. | Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate,  validated methods. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 11.6. | Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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 system  shall be suitable taking account of the method of sterilisation indicated by the manufacturer. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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 for adverse reactions, as required by the applicable conformity assessment procedure  under this Regulation. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 13.  13.1. | Devices incorporating materials of biological origin  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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (a) | donation, procurement and testing of the tissues and cells shall be done in accordance with  Directive 2004/23/EC; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |

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| 13.2.  (a) | 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:  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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 14.  14.1. | Construction of devices and interaction with their environment  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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 14.2.  (a) | Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible:  the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | the risks associated with the possible negative interaction between software and the IT environment within  which it operates and interacts; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (e) | the risks of accidental ingress of substances into the device; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (f) | the risks of reciprocal interference with other devices normally used in the investigations or for the  treatment given; and | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 14.4. | Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can  be done safely and effectively. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 15.  15.1. | Devices with a diagnostic or measuring function  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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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 ). | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 16.  16.1.  (a) | Protection against radiation  General  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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 16.2.  (a) | Intended radiation  Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non  ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices  shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 16.4.  (a) | Ionising radiation  Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying dow | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 17. | Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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 as possible consequent risks or impairment of performance. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 17.2. | 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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). | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 18.  18.1. | Active devices and devices connected to them  For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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 indicated by the manufacturer. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 18.8. | Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 19.  19.1.  (a) | Particular requirements for active implantable devices    Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far  as possible:  risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (b) | risks connected with medical treatment, in particular those resulting from the use of defibrillators or high frequency surgical equipment, and | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 20. | Protection against mechanical and thermal risks | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 21. | Protection against the risks posed to the patient or user by devices supplying energy or substances | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 22. | Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 23.  23.1. | Label and instructions for use  General requirements regarding the information supplied by the manufacturer  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: | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 be described in the documentation supplied with the device. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 23.2.  (a) | Information on the label  The label shall bear all of the following particulars:  the name or trade name of the device; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | the name, registered trade name or registered trade mark of the manufacturer and the address of its  registered place of business; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (f) | where applicable, information labelled in accordance with Section 10.4.5.; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (h) | the UDI carrier referred to in Article 27(4) and Part C of Annex VII; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (i) | an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (k) | an indication of any special storage and/or handling condition that applies; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (l) | if the device is supplied sterile, an indication of its sterile state and the sterilisation method; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (p) | if the device is custom-made, the words ‘custom-made device’; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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’; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (s) | for active implantable devices, the serial number, and for other implantable devices, the serial number or  the lot number. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 23.3.  (a) | Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’)  The following particulars shall appear on the sterile packaging:  an indication permitting the sterile packaging to be recognised as such, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (b) | a declaration that the device is in a sterile condition, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | the method of sterilisation, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | the name and address of the manufacturer, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (e) | a description of the device | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (f) | if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (g) | if the device is custom-made, the words ‘custom-made device’, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (h) | the month and year of manufacture, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (j) | an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| 23.4.  (a) | Information in the instructions for use  The instructions for use shall contain all of the following particulars:  the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (c) | where applicable, a specification of the clinical benefits to be expected. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (d) | where applicable, links to the summary of safety and clinical performance referred to in Article 32; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (e) | the performance characteristics of the device; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (f) | where applicable, information allowing the healthcare professional to verify if the device is suitable and  select the corresponding software and accessories; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (g) | any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 ensurepatient safety and all available methods for achieving those levels of disinfection; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (j) | any requirements for special facilities, or special training, or particular qualifications of the device user  and/or other persons; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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:  — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory  cleaning or disinfection,  — identification of any consumable components and how to replace them,  — information on any necessary calibration to ensure that the device operates properly and safely during  its intended lifetime, and  — methods for eliminating the risks encountered by persons involved in installing, calibrating orservicing devices; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (l) | if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (m) | if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (o) | 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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (p) | 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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (s) | information that allows the user and/or patient to be informed of any warnings, precautions, contra  indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications,  measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:  — 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, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
|  | — 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 electro  magnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures,  pressure, humidity, or temperature, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
|  | — 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, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
|  | — 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, | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
|  | — 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 | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
|  | — 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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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 contra indications, undesirable side-effects and risks relating to overdose; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (u) | in the case of implantable devices, the overall qualitative and quantitative information on the materials and  substances to which patients can be exposed; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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:  — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and  — physical hazards such as from sharps.  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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (w) | for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (aa) | information to be supplied to the patient with an implanted device in accordance with Article 18; | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |
| (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. | *{填写第2列的法规要求是否适用申报产品}（参考示例：A）* | *{填写产品符合第2列性能要求的标准/条款}*  *（参考示例：*  *EN ISO14971:2012，*  *EN ISO 13485:2016*  *Meddev 2.7.1 rev4）* | *{填写与第四列标准/条款对应的报告或文档依据}*  *（参考示例：*  *Risk Management repor，*  *Quality system document*  *Clinical evaluation report）* | *{填写是否符合要求的评论} （参考示例：Compliance）* |

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