Guidance for MDR
Technical Documentation Submissions

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1 Introduction

1 简介

Manufacturers shall ensure the conformity of medical devices being placed on the European market in accordance with the applicable requirements of (EU) 2017/745 Medical Devices Regulation (MDR). Depending on the classification of the device and the conformity assessment route chosen, a full Technical Documentation need to be assessed by a Notified Body. This Technical Documentation submission guidance is aligned to the requirements of (EU) 2017/745 Medical Devices Regulation (MDR), described in detail in Annexes II and III.

制造商应确保投放欧洲市场的医疗器械能够符合（EU）2017/745 医疗器械法规（MDR）。根据器械的分类和符合性评估路径，公告机构需要评估完整的技术文档。本技术文档提交指南符合（EU）2017/745 医疗器械法规（MDR）的要求。详见附录二和附录三。

Tips to get started and Common Feedback
入门提示和常见反馈

TÜV Rheinland and medical device manufacturers are keen to streamline and speed up the review of the Technical Documentation (as part of initial applications, substantial change notifications, renewal applications etc.) and reducing time to certification. The most common reasons for delays in Technical Documentation reviews are:

德国莱茵 TÜV 和医疗器械制造商均希望简化和加快技术文档的评审（作为首次申请、重大变更通知、更新申请等审核的一部分），从而缩短认证时间。造成技术文档评审的延迟，最常见原因如下：

- Incomplete Technical Documentation - not all the information needed for the review were submitted by the manufacturer from the beginning.
- 不完整的技术文档——制造商起初并未提交评审所需的全部信息。
- Unsuitable Technical Documentation Structure - the documentation and information is presented in a manner that it is difficult for TÜV Rheinland to verify compliance of the product in question to the regulation, especially with the**G**eneral **S**afety and **P**erformance **R**equirements (GSPRs) of Annex I
- 不合适的技术文档结构——文档和信息的呈现方式令德国莱茵 TÜV 难以验证相应产品是否符合法规，尤其是附录一的通用安全和性能要求（GSPR）。
- Inaccurate references in the Technical Documentation - References are made to general TD sections (such as “Preclinical Data” or “Labelling”) and not precisely to the applicable source of information.

- 技术文档中的不准确引用——引用的是一般 TD 章节（例如“临床前数据”或“标签”），而非准确引用适用的信息来源。

TÜV Rheinland has prepared this document in order to help facilitate and streamline the Technical Documentation submission and review process which in the end should allow the Notified Body TÜV Rheinland LGA Products GmbH (TRLP) to issue related certificate(s) under the Medical Devices Regulation (EU) 2017/745 (MDR). For the successful processing of MDR applications, one of the critical factors in the process is the quality and structure of Technical Documentations submitted for review. TÜV Rheinland recommends to take time and consider this guidance when creating Technical Documentation(s).

德国莱茵 TÜV 制定了本文件，从而帮助促进和简化技术文档的提交和评审流程，最终使得公告机构—德国莱茵 TÜV 集团 LGA 产品有限公司（TRLP）根据医疗器械法规(EU) 2017/745 (MDR) 颁发相关证书。为了 MDR 申请的顺利进行，关键因素之一是提交评审的技术文档的质量和结构。德国莱茵 TÜV 建议，在创建技术文档时请认真参考本指南。

Please note: this document does not add or change any requirements defined in the MDR, but outlines exemplarily the information and documentation expected to be within the Technical Documentation. It is meant as a guidance, to check the Technical Documentation for completeness before submitting it to the Notified Body. However, TÜV Rheinland may request further documents and information beyond this list in line with the requirements of MDR in the course of the Technical Documentation review.

请注意：本文件没有添加或更改 MDR 中的任何信息，而是举例说明技术文档中的某些信息。作为参考指南，本文件旨在将技术文档提交给公告机构之前协助检查其完整性。但技术文档在评审过程中，德国莱茵 TÜV 可能会根据 MDR 的要求，要求提供此列表之外的更多文件和信息。

2 Submission

2 提交

To begin…

开始之前…

1) Notify your contact person at TÜV Rheinland, that you have a Technical Documentation submission ready for review

   通知您在德国莱茵 TÜV 的联系人：您已准备好提交技术文档以供评审

2) You will receive a quotation if the TD review is not yet covered by an existing order.

如果现有订单尚未包含 TD 评审，您将收到一份报价单。

3) Ensure you have the following ready before moving to the next step:

在进入下一步之前，请确保您已准备好以下各项：

- The current Product List and Application [PL&A] (MDR Annex IX/Annex XI, part A (“QMS part”) and where applicable an application for MDR Annex IX, Chapter II, Section 4)

  当前**产品清单和申请** [PL&A]（MDR 附录九/附录十一，A 部分（“QMS 部分”）以及 MDR 附录九第二章第 4 节的申请（如适用））

- A cover letter accompanying the Technical Documentation submission containing the following information:
  随技术文档提交的附信，其中包含以下信息：
  - Certificate # reference(s) (if known)
    证书#参考（如知晓）
  - Type of review (new product, design change, shelf life extension, etc.)
    评审类型（新产品、设计变更、保质期延长等）
  - Brief product description, including model numbers involved, etc.
    简要的产品描述，包括涉及的型号等。
  - An explanation of what has been submitted and how it demonstrates compliance and,
    对所提交内容及其如何证明符合性的解释以及，
  - for changes to existing certification:
    对于现有认证的变更：
    - what is affected (packaging, material change, sterilisation, etc.)
      受影响的内容（包装、材料变化、灭菌等）
    - what is not affected (along with appropriate justification)
      未受影响的内容（以及适当的理由）
- The TÜV Rheinland (Significant) Change Notification (if applicable):

  德国莱茵 TÜV（重大）变更通知（如适用）：
  TÜV Rheinland | TÜV Rheinland (TÜV.com)

- The signed approved purchase order.

  签署的采购订单。

- The submitted Technical Documentation itself (approved – do not submit drafts!) need to contain objective evidence to demonstrate compliance to the MDR (Annex I (GSPR), Annex II (TD) and Annex III (TD on PMS)).

- 所提交的技术文档（已批准—请勿提交草案！）应包含客观证据，以证明符合MDR（附录一（GSPR）、附录二（TD）和附录三（关于上市后监管的TD））。

  Whenever possible and practical, please provide a product sample of a product in its final packaging together with the Technical Documentation.

  如可能且可行，请在提供技术文档的同时，同时提供一份最终包装好的产品样品。

1) Technical Documentation review can begin upon receipt of a signed purchase order together with all the required application documentation (per Annex IX for initial submissions).

收到经签署的采购订单以及所有所需的申请文档后，可开始对技术文档进行评审（首次提交参考附录九）。

3 Preparing Technical Documentation

3 准备技术文档

MDR is a new legislation, and for initial certification a complete submission with all relevant parts of the Technical Documentation included is required, no matter whether the device was previously certified under the MDD, or AIMDD or not.

MDR 是一项新法规。对于首次认证（无论之前是否已根据 MDD 或 AIMDD 对器械进行认证），都应完整提交技术文档的所有相关部分。

For specific products, the MDR requires a TD review before initial certification. For other types of devices, a review of TDs per device group before certification is required, together with later additional reviews of other devices from the same group based on a sampling approach over the period of certificate validity. The Technical Documentations to be reviewed for initial certification will be determined by TRLP based on the application documents provided, in line with the requirements and guidelines of the MDR.

对于特定产品，MDR 要求在首次认证前进行 TD 评审。对于其他类型的器械，应在认证前对每个器械组抽样进行 TD 评审，随后在证书有效期内，基于抽样方法对同组的其他器械进行额外评审。TRLP 将根据提供的申请文件，按照 MDR 的要求和参考指南来决定首次认证所需评审的技术文档。

Note: For manufacturers with a high number of products, it is recommended to establish a transfer plan to successively transfer the products from MDD/AIMDD to MDR.

注：对于产品数量较多的制造商，建议制定分次计划，依次将产品从 MDD/AIMDD 转换到 MDR。

Furthermore it is crucial that only products which are evidently in compliance with MDR are listed on the application form. Otherwise it causes delays in the review and certification activities.

此外，请在申请表中列出明显符合 MDR 的产品，否则会导致评审和认证的延误。

Particular attention needs to be given to devices that are also machinery, where the Machinery Directive 2006/42/EC is applicable in addition. Relevant requirements of that Directive will also need to be covered given their specificity (refer to Article 1(12)).

请特别注意本身也是机械的器械产品。对于这些器械而言，机械指令 2006/42/EC 也同样适用。考虑到该指令的相关要求具有特殊性，请酌重参考第 1（12）条信息。

The Technical Documentation need to be accompanied by a Declaration of Conformity. For products already in the market under a MDR certificate, a signed Declaration of Conformity

(e.g. for Technical Documentation based on a sampling approach) is expected. For new products, a draft of the Declaration of Conformity for the product needs to be part of the application.

技术文档应附有符合性声明。对于已根据 MDR 证书投放市场的产品，应签署符合性声明（例如，基于抽样方法的技术文档）。对于新产品，申请应包含产品的符合性说明的草案。

The Technical Documentation has to contain consistent information throughout all sections, appendices, and attachments.

技术文档必须在所有章节、附录和附件中包含一致信息。

In case the product in question was not evidently tested itself, applicability of test reports has to be demonstrated for the device in question.

如产品本身未经过测试评审，则必须证明测试报告对相应器械的适用性。

3.1 Language

3.1 语言

In the pre-application phase (i.e. before TÜV Rheinland issues a quotation for the Technical Documentation assessment), we will ask you to provide information regarding the language of the Technical Documentation. It must be an official language of the European Union. We will confirm with you at that stage whether it is feasible for us to perform the assessment in the language in which you would like to submit your Technical Documentation. We strongly recommend that you create the Technical Documentation in the English language.

在预申请阶段（即，在德国莱茵 TÜV 发布技术文档评估报价之前），我们会要求您提供有关技术文档语言的信息。该语言必须是欧盟官方语言。在此阶段，我们将与您确认是否可以使用您希望提交技术文档的语言进行评估。我们强烈建议您使用英语创建技术文档。

Original test reports submitted as part of the Technical Documentation need to be translated accordingly. Documents not submitted in the required language are considered not to be part of the submission and must be excluded from the Technical Documentation and subsequently from any review activities.

原始测试报告作为技术文档提交的一部分，应根据欧盟官方语言的要求进行相应翻译。不符合语言要求的文件将不被认可为提交的一部分，并且必须从技术文档以及后续审核工作中排除。

3.2 Electronic File Format

3.2 电子文件格式

3.2.1 Submission route

3.2.1 提交方式

TÜV Rheinland can provide access to secure data transfer tools for the submission of your Technical Documentation.
德国莱茵 TÜV 可提供信息安全的传输工具，以便提交技术文档。
We recommend you prepare ZIP files for the document upload (or you may split your set of documents in more than one file) while keeping your binder and file structure within the ZIP file(s).
我们建议您准备 ZIP 文件，以便上传文档（或者您可以将您的一组文件拆分为多个文件），同时将您的子文件保留在 ZIP 文件中。
Your TÜV Rheinland office serving you for our Technical Documentation assessment will provide further details on the electronic file submission process.
为您提供技术文档评审服务的德国莱茵 TÜV 办事处将为您提供更多有关电子文件提交的详情。

3.2.2 Format

3.2.2 格式

Annex II of the MDR states “The Technical Documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.” Thus,
MDR附录二的规定“制造商应以清晰、有组织、易于检索以及表达明确的方式提交技术文档以及其总结（如适用），尤其应包括本附录中所列出的要求。”，因此

- Documents shall be provided as paginated, fully searchable, OCR (**O**ptical **C**haracter **R**ecognition) applied and bookmarked PDF files.

  应以分页、可搜索、可文字识别、且带有书签的 PDF 文件形式提供文件。

- Main sections as indicated in MDR Annex II “Technical Documentation” should be bookmarked, as well as any supporting attachments referenced to within the main body (i.e. executive summaries) of the Technical Documentation.

MDR 附录二“技术文档”中所指出的主要章节，以及主体（即：内容摘要）中引用的任何附件，都应添加为书签。

- Clear folder organization and easy navigation will make it easier to find documents and may therefore reduce overall time required for the review.

  清晰的文件夹结构以及便捷的导引，将使文档易于查找，有助于减少评审所需的时间。

- An index or detailed table of contents has to be part of the Technical Documentation.

  技术文档必须包括索引或详细目录。

- File names should be self-explanatory, reflecting the information included within the documents. File names should be appropriately cross-referenced in the TD Overview, see the Annex in this document.

  文件名能够清楚明了的反应文档内容。文件名应在 TD 综述中适当地前后参照。请参考本文件的附录。

- For each main section specified in the MDR Annex II, one PDF file should be submitted. Each section shall contain an executive summary including the references to the accompanying documents, which contain the documented evidence (e.g. reports). These documents have to be either embedded or filed as separate PDFs along with the section.

  针对 MDR 附录二中的每个主要章节，应提交一份 PDF 文件。每个章节都应包含一份内容摘要，包括对随附文件（包含文件证明，例如：报告）的引用。应顺着每个章节，将这些文件整理存档为单独的 PDF 文件组。

- Approvals/signatures are required for any submitted document in the file (signed and dated). No draft versions (except for the Declaration of Conformity and SSCP being part of initial certification submissions) shall be part of the TD submission.

  技术文档中的所有提交文件都需要批准/签署（签署并注明日期）。TD 提交文档不应包含任何草稿版本（除了作为首次认证提交文档一部分的符合性声明和 SSCP）。

3.2.3 Review process

3.2.3 评审流程

The Technical Documentation assessments are performed by assigned reviewer(s) on behalf of the Notified Body TÜV Rheinland LGA Products GmbH.

由指定的评审员代表公告机构—德国莱茵 TÜV 集团 LGA 产品有限公司对技术文档进行评估。

After the date of submission is agreed between manufacturer and TRLP, the manufacturer needs to provide the submission according to section 3.2.1 Submission route to TÜV Rheinland on this agreed date.

制造商与 TRLP 约定提交日期后，应根据第 3.2.1 节要求，在约定日期内向德国莱茵 TÜV 提交文档。

Incomplete TD submissions from manufacturers are one of the most common reasons for questions being raised by our Notified Body reviewers and ultimately can lead to delays in the assessment of TD and the certification process. To make the process more efficient for you and to ensure that we receive a full and thorough submission, we are performing a completeness check. The completeness check is the first step of the TD assessment process before we progress and commence a full in-depth review of the TD. During the review process questions from the reviewers may arise which need to be addressed by additional information to be provided by the manufacturer. In order to maintain an efficient project management, we would like to ask for your understanding that overall project time-lines have to be defined and kept. Therefore, TÜV Rheinland reserves the right to cancel the project and/or decide on further measures if review items still remain open after three rounds.

我方公告机构评审员提出问题的最常见原因之一是：制造商所提交的 TD 文档不完整。这最终可能导致 TD 评估和认证流程大大延迟。为了使流程更高效，并确保我们收到完整、详尽的文档，我们将执行完整性检查。完整性检查是 TD 评估流程的第一步，之后我们才会开始对 TD 进行全面且深入的评审。在评审过程中，评审员可能会提出问题，制造商应及时补充或提供相应信息以解决问题。为了保持高效的项目管理，我们希望您理解到这一点：必须明确和遵守整个项目的时间线。因此，如果评审项目在三轮后仍处于未关闭状态，德国莱茵 TÜV 拥有保留取消项目和/或决定进一步措施的权利。

The completeness check does NOT count as one of the three rounds of questions. However, failure to provide a full set of TD after two attempts may lead to refusal of the application for the subject device(s) or to rescheduling of the review.

完整性检查不作为三轮评审之一。但是如果在两次尝试后未能提供整套 TD，则可能会导致该器械的申请被拒绝，或重新安排评审。

For clarification on questions during the TD review, please provide answers to the corresponding questions within 20 business days after receipt of the questions documented in the “Technical Documentation Assessment MDR - Questions and Answers List”. In cases, where TÜV Rheinland requires further or more detailed evidence of compliance to the MDR, the Technical Documentation must be updated accordingly. To support the review workflow, the revised Technical Documentation

must be accompanied by a revision history indicating any change in comparison to the initial submission. New or revised documents have to be highlighted as such. Also documents, which were declared obsolete have to be indicated. Obsolete or outdated documentation shall not be part of the submission for Technical Documentation review.

如需澄清 TD 评审期间的问题，请在收到“技术文档评估 MDR—问题和回复列表”的 20 个工作日内提供相应答复。如德国莱茵 TÜV 需要进一步或更详细的 MDR 符合性证据，则必须相应地更新技术文档。为支持评审工作流程，修订后的技术文档必须附有修订历史，从而指明与首次提交文档相比的任何更改。全新或修订的文件必须突出显示。同样，必须注明作废的文件。提交的技术文档中不应包含作废或过时的文档。

All answers provided by manufacturers should include a reference to the document number, document name, section and page number that was changed.

制造商提供的所有回复都应引用已更改的文件编号、文件名称、章节和页码。

To reflect the changes made to the Technical Documentation, a redlined document of the “Annex A: Information on TD Deliverables” should be submitted together with the revised Technical Documentation.

为反映对技术文档所做的更改，应提交“附录 A：TD 交付信息”的红线文件，同时提交修订后的技术文档。

Note: If it is not obvious which parts/documents were revised or updated, the re-review of the complete Technical Documentation will be required and will add review times and by that additional review costs.

注意：如果已修订或更新的章节/文件不明显，则需要重新评审完整的技术文档，这会增加评审时间和额外的评审成本。

TRLP has created the “Annex A: Information on TD Deliverables” included with this document, that contains examples of documentation expected in the different sections of the Technical Documentation. However, please refer to MDR Annex II and III for the respective requirements to be addressed.

TRLP 创建了包含在本文件中的“附录 A：TD 可交付信息”，其中包含针对技术文档不同章节的文档示例。请参阅 MDR 附录二和附录三，以便了解相应要求。

3.2.4 Significant changes

3.2.4 重大变更

For devices already reviewed and covered by a certificate, it is crucial to describe the reason for the change(s) including its intended effect(s).

对于已经通过评审并涵盖在证书中的器械，应描述变更原因（包括其预期效应），这一点至关重要。

The TÜV Rheinland Significant Change Notification (SCN) forms may be applicable in certain cases (e.g. new products, design changes, shelf life extensions, manufacturing changes etc, depending on the risk class of the products and their conformity assessment).

德国莱茵 TÜV **重大变更通知**（SCN）表格可能适用于某些情况（例如新产品、设计变更、保质期延长、制造变更等，具体取决于产品的风险等级及其符合性评估）。

For submissions in the context of scope extensions or significant changes, as far as is practical, submissions should be stand-alone and not refer to previous submissions for evidence of compliance. A consolidated revised Technical Documentation is expected, highlighting the changes in the "Annex A: Information on TD Deliverables" and indicating new or revised, obsolete or replaced documents as opposed to the previous already reviewed Technical Documentation revision. Any changes or removals of critical suppliers/subcontractors require a revised Product List and Application, along with a Significant Change Notification, if applicable.

如有范围扩增或重大变更，就实际情况而言，应独立提交文档，并且不应参考先前提交的文档作为符合性证据。最好整理修订一份技术文档，在"附录 A：TD 可交付信息"中强调此变更，并指出全新、修订、作废、或替换的文件，而非之前已评审的技术文档修订版。如变更或移除关键供应商/分包商，则需要修订的**产品清单和申请**，以及**重大变更通知**（如适用）。

If you remove a critical supplier/subcontractor, please also provide justification for their removal.

如果您移除关键供应商/分包商，请同时提供移除的理由。

Note: Before another SCN for a specific Technical Documentation is applied, the previous SCN review needs to be successfully closed and accepted by the certification department.

注意：在申请特定技术文档的另一个 SCN 之前，认证部门应关闭并接受之前的 SCN 评审。

Annex A: Information on TD Deliverables

附录 A：TD 可交付信息

Please use this Annex as follows: Please add into the “Page/section or NA” column the detailed location of the document within the Technical Documentation. Into the column “Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) or in case of N/A include justification” please add the respective information as applicable for the submitted Technical Documentation. You may use the “Check off”, when you have fully completed the respective section.

请按如下方式使用本附录：请在“页/节或不适用”栏中添加文件详细位置。在“所参考证据（文件标题和编号、适用章节等），或在不适用的情况下（包括理由）”栏中，请添加适用于所提交技术文档的相应信息。当您填写完整这两栏后，您可以使用“核对”。

Ref to MDR 参考 MDR	Requirement 要求	Each column to be completed by customer 由客户填写的每栏		
		Page / section or N/A 页/节 或 不适用	Referenced evidence (Document Title & No., Applicable Chapter, Section etc.) Or in case of N/A include justification 所参考证据（文件标题和编号、适用章节等）或 在不适用的情况下（包括理由）	Check off 核对
Application (1) **申请（1）**				
	“Product List and Application MDR (QM part)” (MS-0030360) **“产品清单和申请 MDR（QM 部分）”（MS-0030360）** **and/or** **和/或** **“Product list and Application MDR, Technical Documentation assessment, Annex IX, chapter II” (MS-0030497)** **“产品清单和申请 MDR，技术文档评估，附录九，第二章”（MS-0030497）** **or** **或**		*The following information should be listed on the Product List and Application:* *应在**产品清单和申请**中列出以下信息：* *Identification of the legal manufacturer, who is placing the device on the market. This should be consistent across the device labels, IFU and Declaration of Conformity. The Single Registration Number (SRN) of the legal manufacturer should be identified.* *将器械投放市场的合法制造商。该信息应在器械标签、IFU 和符合性声明中，该标识应保持一致。应确定合法制造商的单一注册号（SRN）。* *The name and location of the EU Authorized Representative should be identified if required. Only one EU Representative should be identified, and this should be consistent across device labels, IFU and Declarations of Conformity. The Single Registration Number (SRN) of the EU Authorized Representative should be identified.* *如需要，应确定欧盟授权代表的姓名和地点。应仅确定一家欧盟代表。同时，在器械标签、IFU 和符合性声明中，该信息应保持一致。应确定欧盟授权代表的单一注册号（SRN）。* *The site(s) responsible for design need to be identified, either external and/or internal.*	

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	"Product List and Application MDR, Product Verification" (MS-0030499) **"产品清单和申请 MDR，产品验证"（MS-0030499）**		*应确定负责设计的场所（无论外部还是内部）。* *All relevant sterilization facilities, internal/external manufacturing facilities, etc., must be listed on your Product List and Application.* *必须在您的**产品清单和申请**中列出所有相关灭菌设施、内部/外部制造设施等。* *In the column "Product name (as listed on label)" the product names need to be listed as identified on the labels. Please complete all lines of the table with the requested information, where applicable.* *在"产品名称（如标签上所列）"栏中，应按照标签上的标识列出产品名称。如适用，请在表格的所有行内填写所要求的信息。*	
	Cover page(s) and table of contents of the Technical Documentation **技术文档的封面和目录**		*As part of the application, provide the cover page of the Technical Documentation.* *提供技术文档的封面，作为申请的一部分。* *Please provide the detailed Table of Contents for Technical Documentation.* *请提供技术文档的详细目录。*	
	Technical Documentation revision history **技术文档修订历史**		*Please provide the revision history of the Technical Documentation, including reason for Technical Documentation revision* *请提供技术文档的修订历史，包括技术文档修订的原因*	
	Presentation of Technical Documentation **技术文档展示**		*Please ensure that the Technical Documentation is provided in a clear, organized, readily electronically searchable and in unambiguous manner* *请确保以清晰、有组织、易于检索以及表达明确的方式提供技术文档*	
Device description and specification (2) **器械说明和性能指标（2）**				
1.1. **(a)**	**General description, including intended purpose and intended users** **综合说明，包括预期目的和预期用户** **(MDN, MDA, MDS-codes (refer to MDCG 2019-14) as well as information whether device is for single use only, multiple use, reprocessing and its number of cycles)**		*The device description should enable understanding of the design, packaging, sterilization, or other characteristics of the device.* *器械说明应确保对器械设计、包装、灭菌或其他特性的理解。* *Sufficient information should be provided to understand the intended purpose of different design features.* *应提供足够的信息，以便了解不同设计特征的预期目的。* *The intended purpose or intended use should provide enough detail to explain the disease conditions the device is intended to treat or monitor.* *预期目的或预期用途应提供充分的细节，从而解释该器械治疗或监测的疾病状况。*	

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	（MDN、MDA、MDS 代码（参见 MDCG2019-14）以及器械是否仅供一次性使用、多次使用、再处理及其循环次数的信息） **(including description of packaging)** **（包括包装说明）**		*Intended use shall be consistent throughout the Technical Documentation (e.g. Instructions for Use, clinical evaluation documentation, etc.). The classification rule of Annex VIII need to match with the intended purpose of the device.* *整个技术文档（例如使用说明、临床评估文档等）中的预期用途应保持一致。附录八的分类规则应与器械的预期用途相匹配。* *Identify the intended users of the device (i.e. medical professionals in a specialty, clinical nurses, lay-persons, etc.). Intended users as claimed shall be substantiated by the clinical evaluation / usability file.* *确认器械的预期用户（即：医疗专业人员、临床护士、非专业人士等）。应使用临床评估/可用性文件对声称的预期用户进行证实。* *Please provide device information on single use, multi-use, or reuse including its number of reprocessing cycles, if applicable.* *请提供关于一次性使用、多次使用或重复使用的器械信息，包括其再处理循环次数，如适用。*	
1.1. **(b)**	**Clear identification of device by unambiguous reference allowing traceability** **通过可追溯的明确参考对器械进行清楚识别** **Basic UDI-DI** **基本 UDI-DI** *(Additional guidance on Basic UDI-DI may be found in the MDCG documents published on the EU Commission website.)* *（可在欧盟委员会网站上发布的 MDCG 文件中找到有关基本 UDI-DI 的其他指南。）* **EMDN code** **EMDN 代码** *(European Medical Device Nomenclature (EMDN code) shall be identified, refer to guidance published on the EU Commission website)* *（应确定欧洲医疗器械命名法（EMDN 代码），参见欧盟委员会网站上发布的指南）*		*Clear identification of device by unambiguous reference, allowing traceability (Basic UDI-DI), together with other traceable reference number (e.g. product code, catalog number, etc.)* *通过可追溯的明确参考（基本 UDI-DI）以及其他可追溯参考号（例如，产品代码、目录编号等）对器械进行清楚识别。* *Information to be consistent also with the information on the labeling.* *信息也应与标签上的信息保持一致。* *Note: Basic UDI-DI need to be consistent with the information on the respective Product List and Application* *注：基本 UDI-DI 应与相应**产品清单及申请**信息保持一致*	
1.1. **(c)**	**Intended patient population and medical condition to**		*Identify the Intended patient population and medical condition to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings*	

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	be diagnosed, treated and/or monitored **(incl. e.g. patient selection criteria, indications, contra-indications, warnings)** **待诊断、治疗和/或监测的预期患者人群和医学病症** **（例如患者选择标准、适应症、禁忌症、警告）**		*确定待诊断、治疗和/或监测的预期患者人群和医学病症以及其他考虑因素，例如患者选择标准、适应症、禁忌症、警告* *The information needs to be consistent throughout the Technical Documentation, especially the clinical evaluation, risk management, labelling, etc.* *整个技术文档中的信息应保持一致，尤其是临床评估、风险管理、标签等。*	
1.1. **(d)**	**Principles of operation of the device and its mode of action, scientifically demonstrated if necessary;** **器械的操作原理及其作用方式（如必要，经科学论证）；**		*The basic principles of operation, including e.g. additional devices/accessories needed, intended users, environment.* *基本操作原理，例如需要的额外器械/配件、预期用户、环境。* *The information needs to be consistent throughout the Technical Documentation, especially clinical evaluation, risk management, labelling, etc.* *整个技术文档中的信息应保持一致，尤其是临床评估、风险管理、标签等。*	
1.1. **(e), (f)**	**Rationale for the qualification of the product as a device,** **justification for the risk class and classification rule (Annex VIII, Chapter III)** **将产品认定为器械的理由，** **风险等级和分类规则的理由（附录八，第三章）**		*The intended use must include the use of the device as a "medical device" as defined by MDR Article 2, unless the device is a product without a medical purpose as listed in MDR Annex XVI.* *预期用途必须包括该器械作为（MDR 第 2 条所定义的）"医疗器械"的用途，除非该器械是 MDR 附录十六中所列出的无医疗用途的产品。* *Please indicate the device classification and the rationale for the classification rule including the sub-rules according to Annex VIII. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.* *请根据附录八说明器械分类和分类规则（包括子规则）的理由。如果基于器械的预期用途，多个规则或者同一规则下的多个子规则适用于同一器械，则应适用生成更高分类的最严格规则和子规则。* *The justification for the device classification should be sufficiently robust in particular in borderlines cases, or in combination products.* *器械分类的理由应该足够可靠，特别是在临界情况下或组合产品中。*	
1.1. **(g)**	**Explanation of any novel features** **任何全新特性的解释**		*A description of novel features of the device need to be provided as part of the device description/specification section.* *应提供器械全新特性的描述，器械描述/规格章节应包含该描述。*	

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			Please explain whether novel features are novel in comparison to other devices in the market and/or novel in comparison to other devices of the manufacturer. *请解释该全新特性的新颖之处是与市场上的其他器械相比还是/以及与制造商的其他器械相比* *Novel features must be accompanied by scientific evidence, as e.g. from clinical investigations* *全新特性必须伴随科学证据，例如：从临床研究中* *(Note: novel features might require a clinical investigation also in case of class IIa or IIb devices.)* *（注意：对于 IIa 类或 IIb 类器械，全新特性也可能需要进行临床调查。）*	
1.1. **(h)**	**Description of all accessories/product intended to be used with the device** **对将与器械一起使用的所有附件/产品的说明**		*Please provide a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.* *请提供与该器械配合使用的器械附件、其他器械和其他非器械产品的说明。* *Evidence need to be provided demonstrating the compatibility of the devices with any applicable accessories/product within the Technical Documentation.* *技术文档中应提供证据证明器械与任何适用附件/产品的兼容性。* *If the accessories are part of the device and as such packaged with the device, please note that the applicable information and evidence of compliance to the MDR are needed for all products/accessories, i.e. the complete content of the packaging.* *如果附件是器械的一部分，并与器械一起包装，请注意所有产品/附件都需要提供适用的信息和符合 MDR 的证据，即：包装的完整内容。*	
1.1. **(i)**	**Description of all configurations/variants of the product** **所有产品的配置/变体的说明**		*All configurations/variants of the product covered by the Technical Documentation need to be clearly identified.* *应明确标识技术文档所涵盖的所有产品的配置/变体。* *Please provide sufficient information to distinguish different variants of the device.* *请提供足够的信息，以便区分器械的不同变体。*	
1.1. **(j)**	**General description of key functional elements (parts/components, formulation, composition, functionality and, where relevant, qualitative and quantitative composition)**		*General description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition.* *关键功能元件的综合说明，例如：其部件/组件（如适用，包括软件）、配方、成分、功能以及，定性和定量组成（如相关）。* *Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;*	

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	关键功能元件的综合说明（部件/组件、配方、成分、功能以及，定性和定量组成（如相关））		*在适当的情况下，这应包括带标签的图示（例如：图表、照片和图纸），清楚地指出关键部件/组件，并包括帮助理解图纸和图表的充分说明；* *Note: This is important for pre-clinical aspects, such as safety concepts, risk management aspects, testing of e.g. physical/mechanical/electrical properties etc., compatibility with other products/accessories, etc. as well as clinical aspects* *注：这对于临床前方面（例如：安全概念）、风险管理方面、物理/机械/电气特性等的测试、与其他产品/附件的兼容性等以及临床方面至关重要*	
1.1. (j)	**Mechanical drawings, photographs** **机械图纸、照片**		*Critical aspects of the specifications including tolerances should be included. This may consist of Critical to Quality aspects, critical dimensions, and a list of critical components/ingredients shall be provided.* *应包括性能指标（含公差）的关键方面。这可能包括质量方面的关键以及关键尺寸，并应提供关键组件/原料清单。*	
1.1. (j)	**Electrical circuits** **电路** **(block diagram)** **（框图）**		*For active medical devices, electrical circuit diagrams shall be a part of the Technical Documentation and should enable the reviewer to understand the electrical safety concept and identification of all relevant electrical components.* *对于有源医疗器械，技术文档应包含电路图，让评审员能够理解电气安全概念并且确定所有相关电气元件。*	
1.1 (k)	**Raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body** **关键功能元件中包含的原材料以及与人体直接接触或间接接触的原材料**		*Please identify the raw materials incorporated into key functional elements of the device including information on any coatings. The nature of contact with the human body (e.g. direct or indirect contact, contact with circulating body fluids etc.) should be clearly identified.* *请确定器械关键功能元件中包含的原材料，包括有关任何涂层的信息。应明确与人体接触的性质（例如：直接或间接接触、接触循环体液等）。* *Please add the Bill of Materials of the device.* *请添加器械的物料清单。*	
1.1. (l)	**Technical specifications as typically claimed in e.g. catalogues, brochures (e.g. features, dimensions, performance attributes, etc.) of the device and the accessories** **目录、手册中特别说明的器械及其附件的技术性能指标（例如：特征、尺寸、性能属性等）**		*Product specifications including tolerances are to be defined for the devices as well as devices and/or accessories, which would typically be used with the device during the procedure (compatibility of the products)* *针对器械以及器械和/或通常在手术过程中与器械一起使用（产品的兼容性）的附件，需要明确包括容差在内的产品性能指标。* *Specifications shall be consistent throughout the Technical Documentation, all labeling and clinical evaluation documentation.* *技术文档、所有标签和临床评估文档中的性能指标应保持一致。*	

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Previous and similar generations of the device (3) **器械的上一代和类似代（3）**				
1.2. **(a)**	**Previous generation produced by the manufacturer** **制造商生产的上一代**		*Previous or similar generations of the product shall be described outlining the differences with the presented product generation.* *应描述产品的上一代和相似代，概述其与当前产品代的差异。* *Information may be important to explain the relevance of data for e.g. the clinical evaluation, **p**ost-**m**arket **s**urveillance (PMS) and **p**ost-**m**arket **c**linical **f**ollow-up (PMCF).* *解释数据相关性的信息可能至关重要，例如：临床评估、上市后监管（PMS）和上市后临床跟踪（PMCF）。*	
1.2. **(b)**	**Similar devices available on the Union or International market** **欧盟或国际市场上在售的类似器械**		*Please provide a list and brief description of any similar devices that are available on the Union or International markets. This may also be important in the interest of e.g. the clinical evaluation, PMS and PMCF.* *请提供欧盟或国际市场上在售的任何类似器械的清单和简要说明。这对于临床评估、PMS 和 PMCF 也至关重要。*	
Labeling (4) **标签（4）** *In regard to language requirements, please refer to MDR, Article 10(11): "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."* *关于语言要求，请参阅 MDR 第 10(11)条："制造商应确保器械附有附录一第 23 节中规定的信息，且信息应采用该器械上市国（欧盟成员国）指定的官方欧盟语言。标签上的详细信息应不可拭除，易于识别，且使预期用户或患者能够清楚理解。"*				
2.1	**Complete set of Labels** **整套标签** (as on the device, on the (e.g. single unit) packaging, sales packaging, transport in case of specific conditions) （如器械标签、（例如单个单元）包装标签、销售包装标签、特定条件下运输标签） (see Annex I, #23.2 and #23.3) （参见附录一，#23.2 和 #23.3）		*Please provide the complete set of labels as used on the device itself, the sterile barrier, the protective/sales packaging, transport packaging etc.* *请提供用于器械本身、无菌屏障、保护/销售包装、运输包装等的整套包装。* *Please clearly identify the position of the respective label (e.g. by photographs) on the final device and all parts of the packaging respectively.* *请分别确认清楚最终器械和所有部分的包装上相应标签的位置（例如：通过照片）。* *Please ensure that labels are one-to-one copies. Please ensure that the copy reflect the label as intended.* *请确保标签和副本是一一对应，并确保副本按预期反映标签。* *If the device has a sterile barrier, clearly identify the label for the sterile package. If any of the packaging is printed with information for the user (including pictures / schematics of the device) this should also be provided.*	

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			如果器械有无菌屏障，请清楚地标识无菌包装的标签。如果任何包装上印有提供给用户的信息（包括器械图片/示意图），则也应提供这些信息。 *Please ensure that any specific requirements of relevant standards or CS are addressed on the labels.* *请确保标签上注明了相关标准或 CS 的任何特定要求。*	
2.2	**Instruction for use (IFU)** **使用说明 (IFU)** (see Annex I, #23.4) （参见附录一，#23.4）		*Please ensure that the information within the IFUs, especially related to the intended purpose, indications, contraindications, and other safety related information such as side effects, warnings are in line with the information within the Technical Documentation such as risk management, clinical evaluation, usability, pre-clinical performance data etc.* *请确保 IFU 中的信息，特别是与预期目的、适应症、禁忌症和其他安全性相关信息（如副作用、警告）与技术文档中的信息一致，例如：风险管理、临床评估、可用性、临床前性能数据等。* *Please ensure that any specific requirements of relevant standards or CS are addressed by the instructions for use. For example EN 60601-1, EN 60601-1-X, EN 60601-2-X, EN ISO 17664, EN ISO 14630 have specific requirements for the Instructions for Use.* *请确保在使用说明中注明相关标准或 CS 的任何特定要求。例如 EN 60601-1、EN 60601-1-X、EN 60601-2-X、EN ISO 17664、EN ISO 14630 对使用说明有特定要求。* *Please define the language requirements for the IFUs based on the target markets and provide the IFU including the respective translations.* *请根据目标市场对 IFU 的语言要求进行明确，并提供 IFU（包括相应的翻译）。* *Some devices incorporate all the information relevant for the patient/user within the IFU itself. Some devices are accompanied by a separate patient handbook with instructions specific to the patient. Such parts of the labeling need to be provided as well, where applicable.* *一些器械在 IFU 中包含与患者/用户相关的所有信息。一些器械附有单独的患者手册，其中包含针对患者的说明。在适用的情况下，也应提供标签的这些部分。* *If a separate physician ' s handbook is relevant for the device, this has to be provided as part of the Technical Documentation as well, where applicable.* *如果单独的医生手册与器械相关，则在适用的情况下，技术文档中也必须包含该手册。* *Please note, that any particular performance claims or product benefits stated in the IFU must be supported by adequate clinical data and/or design testing.* *请注意，任何 IFU 中描述的特定性能声明或产品效益，必须有足够的临床数据和/或设计测试来支持。* *Please provide the IFU in the final print-layout.*	

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			请提供最终打印版式的 IFU。	
2.2	**Electronic Instructions for Use** **电子使用说明** (see Annex I, #23) （参见附录一，#23）		*If electronic Instructions for Use (eIFU) are provided for the device, the eIFU has to be in compliance with the requirements of Regulation 207/2012/EU (MDR, Annex I, #23.1. (f)).* *如果为器械提供电子版使用说明（eIFU），则 eIFU 必须符合法规 207/2012/EU（MDR，附录 I，#23.1.(f)）的要求。* *If applicable, please provide URL of the website where labelling information as relevant is included in Technical Documentation as per Annex I, #23.1* *如适用，请提供网站的 URL。根据附录一#23.1 的规定，技术文档中应包含相关标签信息。*	
Article 18 **第 18 条**	**Implant card and information to be supplied to the patient with an implanted device** **待向患者提供的植入器械植入物卡和信息**		*Please provide the Implant card and information to be supplied to the patient with an implanted device* *请提供向患者提供的植入器械的植入物卡和信息。*	
Design and Manufacturing (5) **设计与制造（5）**				
3. **(a)**	**Information on design stages applied to the device** **有关器械设计阶段的信息**		*Please provide information on the design stages (stages like initial idea, risk analysis, conception, feasibility, design and development, verification and validation activities) applied to the device to be understood.* *请提供用于理解的有关器械设计阶段（例如：初始想法、风险分析、概念、可行性、设计和开发、验证和确认活动等）的信息* *For devices already marketed, please include a history of any major changes to its design, including the reason for design changes.* *对于已经上市的器械，请提供任何重大设计变更的历史记录（包括设计变更的原因）。* *For previously marketed devices certified under the MDD/AIMDD and applying for MDR certification, it is crucial to provide the following:* *对于之前上市的、通过 MDD/AIMDD 认证并申请 MDR 认证的器械，应提供以下信息，这一点至关重要：* - *Any changes in the design of the device as approved under MDD /AIMDD vs. the application under MDR* - *根据 MDD/AIMDD 批准的与根据 MDR 申请的任何器械设计变更* - *a table of previously conducted testing identifying what testing is still relevant to the current version of the device* - *先前完成的测试的表格，识别仍与器械当前版本相关的测试*	

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			Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. *如果未进行新的测试，文档中应包含该决定的理由。*	
3. (b)	**Manufacturing processes, their validation, their adjuvants** **(including identification of the respective manufacturing line)** **制造工艺、验证、佐剂** **（包括对相应生产线的识别）**		*A general description of the manufacturing processes, including manufacturing technologies used and indication of special processes need to be part of the Technical Documentation.* *技术文档应包括制造工艺的综合说明（包括所用制造技术和特殊工艺的说明）。* *The detailed overview may be provided as manufacturing flowchart, including relevant information on e.g. location/site, class of clean room, inspection steps, critical process parameters, etc.* *可通过制造流程图提供详细概述，包括地点/场地、洁净室等级、检查步骤、关键工艺参数等相关信息。* *Please identify the adjuvants used in the manufacturing processes, respectively.* *请识别制造工艺中使用的佐剂。* *If certain critical manufacturing processes are outsourced, please provide a detailed overview of the manufacturing including relevant information on e.g. location/site, class of clean room, inspection steps, critical process parameters, etc.* *如果某些关键制造工艺被外包，请提供制造的详细概述，包括地点/场地、洁净室等级、检查步骤、关键工艺参数等的相关信息。* *Please provide the Master Validation plan and validation reports of processes considered critical for the safety and performance of the device. Please consider this requirement also for critical processes being outsourced. Further information might be requested during the Technical Documentation review and/or during audits.* *请提供主验证计划以及对器械安全性和性能至关重要过程的验证报告。对于外包的关键工艺，也请遵循此要求。在技术文档评审和/或审核期间，可能会要求提供更多信息。*	
3. (b)	**Complete specifications** **完整规范** **(product specification, packaging specification, incoming inspection, continuous monitoring, in process controls, final product testing, installation specification)** **（产品规范、包装规范、进货检验、持续监控、过程控制、最终产品测试、安装规范）**		*Please provide the complete product specification of the finished device.* *请提供成品器械的完整产品规范。* *Please ensure that the following information is provided within the Technical Documentation:* *请确保在技术文档中提供以下信息：* *Incoming inspection of e.g. critical raw materials, (sub-) components: Specifications / acceptance criteria* *关键原材料、（子）组件的来料检验：规范/验收标准* *Continuous monitoring / in-process controls and final product testing: Specifications / acceptance criteria* *持续监控/过程控制和最终产品测试：规范/验收标准*	

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			Installation specification: Specifications and acceptance criteria, where applicable *安装规范：规范和验收标准（如适用）*	
3. **(c)**	**Site(s), including subcontractor(s), supplier(s) where design and manufacturing activities are performed** **进行设计和制造活动的场地（包括分包商和供应商）**		*Please note, the site information, where design and manufacturing activities are performed, must align with the submitted Product List and Application.* *请注意，进行设计和制造活动的场地信息必须与所提交的**产品清单和申请**保持一致。* *Internal and external manufacturing sites as well as all relevant subcontractors and critical suppliers/subcontractors need to be identified.* *应确定内部和外部制造场地以及所有相关分包商和关键供应商/分包商。* *Especially in cases where such certificates are not available, additional audits might need to be performed.* *特别是在没有相关证书的情况下，可能需要执行额外的审核。* *For critical suppliers/subcontractors, please include a justification for identifying the supplier as critical supplier. Please justify changes of subcontractors/suppliers, respectively.* *对于关键供应商/分包商，请提供将该供应商标识为关键供应商的理由。请分别说明分包商/供应商的变更。*	
6.2 (e)	**In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps.** **针对无菌或规定微生物条件下投放市场的器械，对相关制造步骤中环境条件的说明。**		*Environmental conditions for the relevant manufacturing steps need to be identified. (e.g. Class of cleanroom)* *应确定相关制造步骤的环境条件（例如：洁净室等级）。* *Refer to applicable parts of the EN ISO 14644 series.* *请参阅 EN ISO 14644 系列的适用部分。* *Bioburden test results (methods/procedures) and evidence of bioburden testing need to be included for the products in question.* *应包括相应产品的生物负荷检查结果（方法/程序）和生物负荷检查证据。* *(see e.g. Annex I, #11.6)* *（参见附录一，#11.6）*	
General Safety and Performance Requirements (6) **通用安全与性能要求（6）**				
4. (a)-(d)	**“General safety and performance requirements” document** **“通用安全与性能要求”文件**		*Please provide a “General safety and performance requirements” document structured according to MDR, Annex II Section 4:* *请提供根据 MDR 附录二第 4 节构建的“通用安全通用与性能要求”文件：* - *Containing a decision column on applicable versus not applicable for each clause/sub-clause of MDR, Annex I*	

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			包含适用与不适用于附录一 MDR 每个条款/子条款的决策栏 - *Containing a decision column on each clause/sub-clause of MDR, Annex I that apply to the device and an explanation as to why others do not apply* *包含适用于器械的附录一 MDR 每个条款/子条款的决策栏，以及其他不适用的解释* - *Containing a column to add methods used to demonstrate conformity with each clause/sub-clause of MDR Annex I* *包含添加方法（用于证明符合 MDR 附录一每个条款/子条款）的一栏。* - *Containing a column to add applied standards, **C**ommon **S**pecification CS or others for each clause/sub-clause of MDR respectively* - *包括分别为 MDR 每个条款/子条款添加应用标准、通用规范 CS 或其他的一栏* - *Containing a column to add the precise identity of the controlled documents offering evidence of conformity with each applied standard, CS or other method applied and a cross-reference to the location of such evidence within the full Technical Documentation and, if applicable, the summary Technical Documentation for each clause/sub-clause of MDR, Annex I* *包含用于添加准确识别受控文件的一栏，这些文件提供每个应用标准、CS 或其他应用方法的符合性证据、对此类证据在完整技术文档中位置的前后参照、MDR 附录一每个条款/子条款的技术文档摘要（如适用）* *Please provide an overview of applicable standards/common specification/etc. and indicate, which of these were (fully or partially) applied, including version (state of the art).* *请提供适用标准、通用规范等的概述，并指出其中哪些已（全部或部分）得到应用，包括版本（最新技术）。* *If outdated standards were applied, a gap assessment needs to be provided to demonstrate state of the art. If no new testing is deemed required, a justification needs to be provided.* *如果应用过时的标准，则应提供差距评估，以便证明最新技术。如果认为不需要进行新的测试，则应提供理由。* *Refer to additional applicable standards, and/or directives – e.g. Machinery, EMC, RoHS, scientific opinions, guidance as necessary to show state of the art.* *请参阅其他适用标准和/或指令—例如：展示最新技术所需的机械、EMC、RoHS、科学意见、指南。*	
Benefit-Risk Analysis and Risk Management (7) **风险利益分析和风险管理（7）**				

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5. (a)-(b)	**Risk Management:** **风险管理：** **Risk management plan** **风险管理计划** (Refer to Annex. I, #3a) （参阅附录一，#3a） **Risk assessment including risk control** **包括风险控制的风险评估** (Refer to Annex. I, # 3b-e, #4) （参阅附录一，#3b-e，#4） **Information from production phase and PMS on hazards and the frequency of occurrence thereof, risk acceptability including possibly adaption of control measures** (refer to Annex I, #3 f) 来自生产阶段和 PMS 的关于危害及其发生频率、风险可接受性的信息，包括可能采用的控制措施（参阅附录一，#3 f） **Overall residual risk evaluation including residual risk evaluation** (refer to Annex I, #8) 包括剩余风险评估在内的整体剩余风险评估（参见附录一，#8）		*Please refer to the MDR requirements like Annex I, clauses 1-9.* *请参阅 MDR 要求，如附录一第 1-9 条。* *Please provide the relevant risk management file documents, especially the Risk Management Plan, Risk Management Report. The system used for qualitative or quantitative categorization of probability of occurrence of harm and severity of harm shall be recorded in the risk management file.* *请提供相关风险管理文件，尤其是风险管理计划、风险管理报告。应在风险管理文件中记录用于对危害发生概率和严重程度进行定性或定量分类的系统。* *Please clearly indicate whether the risk management process is based on EN ISO 14971.* *请明确说明风险管理流程是否基于 EN ISO 14971。* *Please provide evidence that a safety concept in accordance with MDR, Annex I, clause 4 is applied.* *请提供证据证明应用了符合 MDR 附录一第 4 条的安全性概念。* *The risk management file needs clearly to reflect the interface between the risk management process and pre-clinical and clinical evaluations performed by the manufacturer (refer to Annex VII, 4.5.4(c) and 4.5.5.)* *风险管理文件应清楚地反映风险管理流程与制造商所进行的临床前和临床评估之间的接口（参阅附录七中 4.5.4(c)和 4.5.5。）*	
Annex I, 5 **附录一，5**	**Usability Evaluation** **可用性评估** See e.g. Annex I, #14.6, #21.3, #22.1, #22.2, #23.1a 参见附录一 #14.6、#21.3、#22.1、#22.2、#23.1a		*Please refer to the MDR requirements like Annex I, clauses #14.6, #21.3, #22.1, #22.2, #23.1a* *请参阅 MDR 要求，如附录一，#14.6、#21.3、#22.1、#22.2、#23.1a* *Please refer to EN 62366-1.* *请参阅 EN 62366-1。* *For ease of review, please also provide a use flow-chart for the device in question.* *为便于评审，请提供相应器械的使用流程图。*	

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Pre-clinical (product validation/performance) data (8) **临床前（产品验证/性能）数据 (8)** *Note in general: In case testing is not performed on each product variant, the representative character of the tested product for a product range needs to be demonstrated considering the worst case approach.* *注意一般而言：如果未对每个产品变体进行测试，则应考虑最坏情况方法，应证明产品范围内测试产品的代表性特征。* *Furthermore test results must be provided in SI units.* *此外，必须以 SI 单位提供测试结果。* *Determined sample sizes are to be justified for all testing, respectively.* *所确定的样本尺寸应分别用于所有测试。* *Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision.* *如果未进行新的测试，文档中应包含该决策的理由。* *Please provide an executive summary, outlining the performed tests, test specification, test results incl. standard deviation, and conclusions drawn. The test reports themselves need to be attached to the executive summary report,* *请提供内容摘要，概述所进行的测试、测试规范、测试结果（包括标准偏差和结论）。应将测试报告本身附在摘要报告中。*				
	Test laboratory accreditation (GLP/EN ISO 17025) **测试实验室认证（GLP/EN ISO 17025）**		*In general, for the test laboratory/-ies used for testing of e.g. electrical safety, biocompatibility, bioburden, sterilization residuals, sterility tests etc. please provide the accreditation/designation of the respective laboratory.* *一般而言，针对用于测试电气安全、生物相容性、生物负荷、灭菌残留物、无菌测试等的测试实验室，请提供相应实验室的认证/名称。* *Please include the qualification of the test laboratories (e.g. accreditation including its attachment to accreditation) valid at the time of testing.* *请包括测试时有效测试实验室的资质（例如：包括认证及其附件）。*	
6.1. a	**Evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications** **对适用于该器械的公开文献的评估，考虑到其预期用途，或类似器械（与该器械的临床前安全性及其规范的相符的）**		***Please provide the evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications*** ***请提供对适用于该器械的公开文献的评估，考虑到其预期用途，或类似器械（与该器械的临床前安全性及其规范的相符的）***	
6.1. (a-b)	**Chemical characterization** **化学特性描述**		*Please include the chemical characterization.* *请包括化学特性描述。*	

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6.1. (a-b)	**Biocompatibility including identification of all materials in direct or indirect contact with the patient and user Biological/chemical tests/studies in animal models** **生物相容性，包括确定与患者和用户直接或间接接触的所有材料** **动物模型中的生物/化学测试/研究**		*The biocompatibility evaluation report shall be written by an expert in this field and shall document the test strategy and shall include a rationale for selection and/or waiving of biocompatibility tests and the use of any additional data to complete the evaluation. Include the overall biological safety conclusions for the medical device.* *应由该领域的专家编写生物相容性评估报告。该报告应记录测试策略，并应包括选择和/或放弃生物相容性测试以及使用任何额外数据来完成评估的理由。该报告包括对该医疗器械整体生物安全的结论。* *In the case of test results are fail, a scientific based justification must be included why nevertheless sufficient biocompatible properties of the device is deemed to be demonstrated.* *如果测试结果未通过，必须包括基于科学的理由（认为该器械具有充分生物相容性的原因）。* *Please ensure that the biological properties of the finished device in its final packaging is demonstrated by sufficient biocompatibility data considering the nature and duration of body contact.* *考虑到身体接触的性质和持续时间，请确保通过充分生物相容性的数据证明最终包装中成品器械的生物学特性。* *Data shall also demonstrate biocompatibility at the end of shelf life and over the life-time.* *数据还应证明在保质期结束时以及整个生命周期内的生物相容性。* *The referenced biocompatibility test reports need to be attached to the biocompatibility evaluation report.* *生物相容性评估报告需附上参考的生物相容性测试报告。* *Please demonstrate the qualification of the personal involved in the biocompatibility assessment (planning, execution, analysis).* *请证明参与生物相容性评估（计划、执行、分析）的人员资格。*	
6.1. (a-b)	**Performance and safety (physical/mechanical tests)** **性能和安全（物理/机械测试）**		*Include all necessary data to support t=0 and data supporting performance and safety of the device up to the end of the product lifetime (see also Annex I, #6).* *包括支持 t=0 的所有必要数据以及支持在产品寿命结束前器械性能和安全性的数据（另见附录一，#6）。* *In case accelerated aging data are used, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25° C). Estimated dates by which the related real time aging data are available need to be provided, including interim time-points. Physical safety includes mechanical characteristics and safety related to conditions occurring under normal conditions of the intended use of the device, which may include e.g. ionizing and/or non-ionizing radiation.* *如果使用加速老化数据，则计算时应考虑使用相应的存储温度（例如：对于室温，环境温度为 25° C）。应提供相关实时老化数据可用的估计日期，包括临时时间点。物理安全包括与器械预期使用*	

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			正常条件下所发生条件相关的机械特性和安全。其中可能包括电离和/或非电离辐射。	
6.1. (a-b)	**Electrical safety and electromagnetic compatibility** **电气安全和电磁兼容性**		*Provide all relevant evidence of compliance with the appropriate and current standards (applicable parts of the EN 60601 series)* *提供符合适当和现行标准的所有相关证据（EN 60601 系列的适用部分）*	
6.1. (a-b)	**Software verification and validation including information on all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacture** **软件验证和确认，包括有关所有不同硬件配置的信息，以及制造商所提供信息中确定的操作系统（如适用）**		*Full lifecycle management must be demonstrated and provided as appropriate for the risk class of the software. EN ISO/IEC 62304 is the state-of-the-art approach.* *必须根据软件风险等级证明和提供完整的生命周期管理。EN ISO/IEC 62304 是最新水平的方法。* *Note: Test report form may not be sufficient by itself.* *注：仅有测试报告单，可能不够充分。*	
6.1. (a-b)	**Simulated use testing/testing in animal models** **模拟使用测试/动物模型中的测试**		*Simulated use testing might have been performed as part of design verification, performance testing, design validation, usability testing or clinical studies. Please provide evidence of such type or any other type of simulated use testing here or refer to test reports provided as part of other sections of the TD.* *设计验证、性能测试、设计确认、可用性测试或临床研究包含可能已进行的模拟使用测试。请在此处提供此类或任何其他类型模拟使用测试的证据，或参考所提供的测试报告（作为 TD 其他章节一部分）。* *Simulated use testing may also be performed by testing in animal models.* *也可以通过动物模型中的测试，进行模拟使用测试。* *Simulated use testing and testing in animal models may also contribute to clinical evaluation.* *模拟使用测试和动物模型中的测试也可能有助于临床评估。* *Simulated use tests may also include simulation of product life time.* *模拟使用测试还可能包括模拟产品寿命。*	
Shelf life/ Transport simulation (9) **保质期/运输模拟（9）**				
6.1. (b)	**Product and packaging stability Tests, (up to the claimed shelf life)**		*It needs to be demonstrated that the product incl. its packaging meets its specification after aging.* *应证明产品（包括其包装）在老化后符合其性能指标。*	

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	产品和包装稳定性测试，（直至声称的保质期） See e.g. Annex I #7, #11.3, #11.4 参见附录一#7、#11.3、#11.4		*Product stability data must be included up to and including the labeled shelf life.* *必须包括产品稳定性数据，并涵盖标注的保质期。* *In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25 ° C).* *如果最初使用加速老化数据，则计算时应考虑相应的存储温度（例如：对于室温，环境温度为25 ° C）。* *Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.* *应提供相关实时老化数据可用的估计日期，包括临时时间点（如适用）。*	
6.1. (b)	**Transport evaluation/validation (product and packaging)** **运输评估/确认（产品和包装）** See e.g. Annex I #7, #11.3, #11.4 参见附录一#7、#11.3、#11.4		*Please provide the transport evaluation/validation for the product in its packaging.* *请提供包装好的产品的运输评估/确认。* *Please consider the respective environmental challenges of the product transport and justify the chosen test conditions (e.g. as required by transportation standards) accordingly.* *请考虑产品运输的相应环境挑战，并相应地证明所选测试条件（例如，运输标准中所要求）的合理性。* *Transportation of the product to the end user must not have an impact on the quality, safety or performance of the device.* *将产品运输到最终用户的过程中，不得对设备的质量、安全性或性能产生影响。* *The sterile barrier packaging validation related section can be found above, see Section 6.1(b) "Product and packaging stability tests".* *有关无菌屏障包装确认的章节，参加上文。参见第6.1(b)节"产品和包装稳定性测试"。*	
Specific cases **特定情况**				
Devices incorporating a substance considered to be a medicinal product (10) **包含被认为是药用产品的物质的器械（10）**				
6.2. (a)	**Medicinal substances(Annex IX, #5.2)** **药用物质（附录九，#5.2）**		*Ensure quality, safety and usefulness of the substance with methods specified in Directive 2001/83/EC, Annex I.* *使用指令 2001/83/EC 附录一中指定的方法确保物质的质量、安全性和有用性。* ***MDCG 2020-12:** Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues*	

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			MDCG 2020-12：有关当局就包含可被视为药用产品并具有辅助作用的物质的器械以及使用 TSE 易感动物组织制造的器械进行咨询的过渡条款指南	
	Source of medicinal substance (including manufacturer) **药用物质来源（包括制造商）**		*Unequivocally identify the source of the medicinal substance* *明确识别药用物质的来源*	
	Drug Master File (DMF) available for review **可供评审的药物主文件（DMF）**		*Please indicate, which Competent authority is preferred to be consulted. Please indicate, which Competent authority has reviewed the DMF, if any.* *请说明更愿意咨询哪个主管当局。请说明哪个主管当局评审了 DMF（如果有）。* *Please add a Letter of Access for the DMF from the DMF holder (manufacturer of the medicinal substance)* *请添加 DMF 持有人（药用物质制造商）的 DMF 授权信* *Please provide the documents in the drug consultation documentation, which is required by the proposed competent authority.* *请提供药物咨询文档中的文件，这是拟议的主管当局所要求的。*	
	Test(s) conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device. **为评估其安全性、质量和有用性而进行的测试（同时考虑到器械的预期用途）**		*Please detail, where in the Technical Documentation and where in the drug consultation documentation the evidence on safety, quality and usefulness, taking account of the intended purpose of the device can be found* *请详细说明在技术文档和药物咨询文档的何处可找到有关安全性、质量和有用性的证据（同时考虑到器械的预期用途）*	
	usefulness of the substance as part of the device taking account of the intended purpose of the device **作为器械一部分的物质的有用性（考虑到器械的预期用途）**		*Please detail, where in the Technical Documentation and where in the drug consultation documentation the evidence on usefulness of the substance as part of the device taking account of the intended purpose of the device* *请详细说明在技术文档和药物咨询文档的何处可找到作为器械一部分的物质有用性的证据（考虑到器械的预期用途）*	
Devices incorporating materials of animal origin (11) **包含动物源材料的器械（11）**				
6.2. (b)	**Materials of animal origin** **动物源材料**		*Please ensure that the requirements of MDR, Annex I, clause #13.1, # 13.2 and 13.3 are addressed in this part of the Technical Documentation.*	

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			请确保 MDR 附录一第#13.1、#13.2 和 13.3 条的要求在技术文档的这一部分中进行说明。	
	non-viable tissues or cells of animal origin, or their derivatives utilized in the manufacturing **用于制造的动物来源的非活组织或细胞，或其衍生物**		*Please identify non-viable tissues or cells of animal origin, or their derivatives utilized in the manufacturing of the device* *请确定用于器械制造的动物来源的非活组织或细胞，或其衍生物*	
	animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues **已经受兽医控制的动物，即适合于组织的预期用途的动物** (Annex I, #13.2a) （附录一，#13.2a）		*Please identify whether the animals were subject of appropriate veterinary controls* *请确定动物是否接受了适当的兽医控制*	
	Information about the geographical origin of the animals retained by the manufacturer **制造商保留的动物地理来源信息** (Annex I, #13.2a) （附录一，#13.2a）		*Is the information about geographical origin of the animals retained by the manufacturer of the device?* *器械制造商是否保留动物的地理来源信息？*	
	Sourcing, processing, preservation, testing and handling carried out so as to provide safety for patients, users and, where applicable, other persons **获取、处理、保存、测试和操作，从而为患者、用户和其他人员（如适用）提供安全保障** (Annex I, #13.2b) （附录一，#13.2b）		*Please provide evidence that the sourcing, processing, preservation, testing and handling is carried out so as to provide safety for patients, users and, where applicable, other persons.* *请提供证据证明获取、处理、保存、测试和操作，从而为患者、用户和其他人员（如适用）提供安全保障。*	
	Safety with regard to viruses and other transmissible agents addressed by		*Please provide evidence that the safety with regard to viruses and other transmissible agents is addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of*	

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	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; **通过在制造过程中实施经过验证的消除或病毒灭活方法，来解决病毒和其他传播因子的安全问题，除非使用此类方法会导致不可接受的降解，从而损害器械的临床效益；** (Annex I, #13.2b) （附录一，#13.2b）		*such methods would lead to unacceptable degradation compromising the clinical benefit of the device.* *请提供证据证明通过在制造过程中实施经过验证的消除或病毒灭活方法，来解决病毒和其他传播因子的安全问题，除非使用此类方法会导致不可接受的降解，从而损害器械的临床收益；*	
	Requirements on devices manufactured utilizing tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 **法规（EU）722/2012 中提及的对利用动物来源的组织或细胞或其衍生物所制造器械的要求**		*Please detail whether the device is manufactured utilizing tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012.* *请详细说明按照法规（EU）722/2012 是否利用动物来源的组织或细胞或其衍生物进行器械制造。* *Please provide details on the material of animal origin and demonstrate compliance to Regulation (EU) No 722/2012.* *请提供有关动物源材料的详细信息，并证明符合法规（EU）722/2012。*	
Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body (12) **由人体吸收或局部扩散至人体中的物质或物质组合构成的器械（12）**				
6.2. (c)	**Materials intended to be absorbed by or locally dispersed in the human body** (Annex I, #12.2) 旨在由人体吸收或局部扩散至人体中的材料 （附录一，#12.2）		*Please refer to MDR, Annex I # 12.2 to address the specific aspects related to substances or combinations of substances that are absorbed by or locally dispersed in the human body* *请参阅 MDR，附录一# 12.2，以说明与人体吸收或局部扩散至人体中的物质或物质组合相关的具体方面*	
	absorption, distribution, metabolism and excretion tests		*For the evaluation of absorption, distribution, metabolism, excretion, please refer also to the requirements of Annex I to Directive 2001/83/EC*	

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	吸收、分布、代谢和排泄试验		*有关吸收、分布、代谢、排泄的评估，请参阅指令 2001/83/EC 附录一的要求*	
	possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions **考虑到目标人群及其相关医疗条件，这些物质或其在人体内的代谢产物与其他器械、医药产品或其他物质可能发生相互作用**		*For the evaluation of local tolerance, please refer also to the requirements of Annex I to Directive 2001/83/EC* *有关局部耐受性的评估，请参阅指令 2001/83/EC 附录一的要求*	
	local tolerance **局部耐受性**		*For the evaluation of local tolerance, please refer also to the requirements of Annex I to Directive 2001/83/EC* *有关局部耐受性的评估，请参阅指令 2001/83/EC 附录一的要求*	
	toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device. **毒性，包括单剂量毒性、重复剂量毒性、遗传毒性、致癌性以及生殖和发育毒性，具体取决于器械的暴露水平和性质。**		*For the evaluation, please refer also to the requirements of Annex I to Directive 2001/83/EC* *有关评估，请参阅指令 2001/83/EC 附录一的要求*	
	Justification in case above mentioned studies on absorbable or locally dispersed materials are not performed/provided **未执行/提供上述关于可吸收或局部扩散材料研究的理由**		*Please add a scientific based justification in case related tests on absorbable or locally dispersed materials are not performed/provided* *如果未执行/提供对可吸收或局部扩散材料的相关测试，请添加基于科学的理由*	
Devices containing CMR or endocrine-disrupting substances (13)				

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含有 CMR 或内分泌干扰物质的器械（13）				
6.2. (d)	**Substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) and/or endocrine disrupting substances** **致癌、致突变或生殖毒性（CMR）物质和/或内分泌干扰物质**		*Please refer to MDR, Annex I # 10.4.1 to address the specific aspects related to CMR and/or endocrine-disrupting substances* *请参阅 MDR 附录一#10.4.1，以说明与 CMR 和/或内分泌干扰物质相关的具体方面*	
	CMR concentration above 0,1 % weight by weight (w/w) where justified pursuant to Annex I, #10.4.2: **根据附录一#10.4.2，CMR 浓度高于 0.1%重量比（w/w）**		*Please refer to MDR, Annex I # 10.4.2 to address the specific aspects related to CMR and/or endocrine-disrupting substances* *请参阅 MDR 附录一#10.4.2，以说明与 CMR 和/或内分泌干扰物质相关的具体方面* *In regard to labeling requirements please refer to MDR, Annex I # 10.4.5* *关于标签要求，请参阅 MDR 附录一# 10.4.5*	
Devices with a measuring function (14) **具有测量功能的器械（14）**				
6.2 (f)	**Devices with a measuring function including evidence of accuracy as specified** **具有测量功能的器械，包括规定精度的证据**		*Please provide a description of the methods used in order to ensure the accuracy as given in the specifications* *请描述用以确保性能指标中给出的精度的方法* *Please refer to e.g. Annex I #14.2 (g), #14.6, #15* *请参阅附录一#14.2 (g)、#14.6、#15*	
Combination, connection to other devices (15) **组合、连接到其他器械（15）**				
6.2. (g)	**Accessories and detachable parts, other devices needed to operate as intended, including proof of safety and performance of the combination** **附件和可拆卸部件、按预期操作所需的其他器械，包括组合安全性和性能证明**		*Please provide a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacture.* *请提供对这种组合/配置的描述，包括在连接到任何此类器械时符合一般安全和性能要求的证据（考虑到制造商指定的特性）。* *Please ensure that the labelling reflects the respective information.* *请确保标签反映了相应的信息。* *Please also refer to e.g. Annex I #14.1, #17.3, #23.4 (q), Annex II, 1.1 (h)* *另请参阅附录一#14.1、#17.3、#23.4(q), 附录二 1.1 (h)*	
Sterile devices or devices in defined microbiological condition (16) **无菌器械或规定微生物条件的器械（16）**				
6.1. (b)	Microbiological characterization:		*Information on the biological contamination of the device needs to be provided like:*	

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	微生物特性描述： bioburden testing, 生物负荷测试， pyrogen testing 热原测试		*应提供有关器械生物污染的信息，例如：* *- Evidence of microbiological characterization, which is performed as part of the sterilization validation.* *-微生物特性描述（作为灭菌确认的一部分）的证据。* *- Bioburden and pyrogen test reports, including the information on the recovery rate.* *—生物负荷和热原测试报告，包括回收率信息。* *- Information on the respective alert and action limits.* *-有关相应警报和动作限制的信息。*	
6.2. (e)	Packaging validation (for sterile devices) 包装确认 （针对无菌器械）		*If the device is placed in a primary/secondary package that is intended to be the sterile barrier, please provide the following:* *如果器械放置在作为无菌屏障的初级/二级包装中，请提供以下信息：* *- Microbial barrier integrity of materials and seals for packaging* *微生物屏障完整性 和包装密封性* *- Packaging validation reports reflecting all seals* *反映所有密封件的包装确认报告* *- maintenance of sterility up to the labeled shelf-life* *- (refer to EN ISO 11607-1)* *- 保持无菌直至标示的保质期* *（参阅 EN ISO 11607-1）* *- Packaging system performance testing (handling, distribution, storage)* *- 包装系统性能测试（搬运、配送、储存）* *In case accelerated aging data are used initially, the respective storage temperature needs to be considered for calculation (e.g. for room temperature the ambient temperature is 25° C).* *如果最初使用加速老化数据，则计算时应考虑相应的存储温度（例如：对于室温，环境温度为 25° C）。* *Estimated dates by which the related real time aging data will be available need to be provided, including interim time-points, where applicable.* *将提供相关实时老化数据可用的估计日期，包括临时时间点（如适用）。*	
	Description of sterilization method 灭菌方法描述 (including location) （包括地点）		*Please note, description and location must align with the information provided in the Product List and Application.* *请注意：和地点必须与**产品清单和申请**中提供的信息一致。* *Please provide copies of the EN ISO 13485 certificates including the relevant scope for the performed sterilization activities of the sterilization facility/ies.* *请提供 EN ISO 13485 证书的副本，包括灭菌设施所执行灭菌活动的相关范围。*	
	Validation of sterilization method 灭菌方法的确认		*Key characteristics of the sterilization process and the related initial validation and all relevant revalidations including all attachments need to be provided (according to the respective sterilization standards).* *应提供灭菌过程的关键特性以及相关首次确认和所有相关重新确认（包括所有附件）（根据相应的灭菌标准）。*	

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			Please ensure that the approach for the sterilization validation is clearly defined. *请确保明确规定了灭菌确认的方法。* *In case the device in question was not part of the sterilization validation, the suitability of the sterilization validation for sterilization of the device needs to be demonstrated.* *如果灭菌确认中未包括该器械，则应证明灭菌确认对该器械灭菌的适用性。* *Please provide the documentation according to the applicable standard for respective sterilization method.* *请根据相应灭菌方法的适用标准提供文档。*	
	Testing for sterilant residues 灭菌残留检测		*Test reports on the sterilization residuals need to be provided.* *应提供灭菌残留物的检测报告。* *The testing needs to be performed on device samples under consideration of a worst case approach.* *应考虑最坏情况方法对器械样品进行测试。* *In case multiple sterilization cycles shall be allowed, the residual test results are to be provided according to the maximum number of sterilization cycle allowed.* *如果允许多次灭菌循环，应按允许的最大灭菌循环次数提供残留试验结果。* *Refer to applicable standards like EN ISO 10993-7.* *请参阅适用标准，如 EN ISO 10993-7。*	
	Usage of preservatives 防腐剂的使用		*In case preservatives are used, effects such as effects on biocompatibility of the finished device need to be evaluated. To be considered e.g. storage up to the labelled shelf-life.* *如果使用防腐剂，则应评估对成品器械的影响如对生物相容性的影响，并考虑储存至标示的保质期。* *The potential impact on the patient and/or user and related risk / benefits of using preservatives needs to be evaluated.* *应评估使用防腐剂对患者和/或用户的潜在影响以及相关风险/效益。*	
	Reprocessing / sterilization before use 使用前的再处理/灭菌		*In case reprocessing is claimed, the respective validation of the reprocessing process needs to be provided.* *如果要求再处理，则应提供对再处理过程的相应确认。* *The instructions provided in the IFU/user manual has to be substantiated by validation for cleaning / disinfection / sterilization / drying.* *必须通过清洁/消毒/灭菌/干燥确认来证实 IFU/用户手册中提供的说明。* *Refer to EN ISO 17664. Please refer to e.g. Annex I, #11.2, #23.4m, #23.4n.*	

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			请参阅 EN ISO 17664。请参阅附录一，#11.2、#23.4m、#23.4n。	
	Aseptic filling / sterilization filtration 无菌灌装/灭菌过滤		*A description of the aseptic filling process has to be provided and the type of validation justified. Overall process validation is required, including the parameters and monitoring planned.* *必须提供对无菌灌装流程的描述，且确认类型应具有合理性。应对整个过程进行确认，包括计划的参数和监控。* *Refer to EN ISO 13408-1 / EN ISO 13408-2.* *请参阅 EN ISO 13408-1/EN ISO 13408-2。*	
Clinical data (17) **临床数据（17）**				
6.1. (c)	**Clinical evaluation report and clinical evaluation plan** **临床评估报告和临床评估计划** **Clinical investigation** **临床调查**		*For clinical evaluation, please refer to MDR, Annex XIV, Part A.* *关于临床评估，请参阅 MDR 附录十四 A 部分。* *Documents expected as part of the clinical documentation:* *预期作为临床文件一部分的文件：* - *Clinical evaluation report (CER)* - *临床评估报告（CER）* - *All attachments to CER (e.g. author CVs, Declaration of conflict of interest)* - *CER 的所有附件（例如：作者简历、利益冲突声明）* - *Clinical evaluation plan (CEP), including the attachments* - *临床评估计划（CEP），包括附件* - *Full text copies of the relevant published literature* - *相关已发表文献的全文副本* - *Literature search protocol* - *文献检索协议* - *Literature search reports* - *文献检索报告* - *Full list of retrieved articles* - *检索文章的完整列表* - *Full list of excluded articles, with reasons for exclusion* - *排除文章的完整列表，以及排除原因* - *Promotional material* - *宣传材料* *Please consider the guidance laid down in:* *请考虑以下指南：* ***MDCG 2020-5** Guidance on clinical evaluation – Equivalence* ***MDCG 2020-5** 临床评估指南——等效性* ***MDCG 2020-6** Guidance on sufficient clinical evidence for legacy devices* ***MDCG 2020-6** 有关遗留器械足够临床证据的指南*	

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			Note: CER content will be reviewed and the review documented under application of the content required for the CEAR, ref. ***MDCG 2020-13*** *Clinical evaluation assessment report template* *注：将对 CER 内容进行评审，并根据 CEAR 所需内容的申请，对评审进行归档。参考 MDCG 2020-13 临床评估报告模板* *Please justify the personal conducting and approving the clinical evaluation and demonstrate their qualification including their product and procedure related expertise.* *请说明进行和批准临床评估人员的合理性，并证明此类人员的资格，包括其产品和程序相关的专业知识。* *For clinical investigations, please refer to MDR, Annex XV.* *有关临床研究的信息，请参阅 MDR 附录十五。* *If clinical investigations (including post market clinical follow up studies) have been conducted:* *如果已进行临床调查（包括上市后临床跟踪研究）：* - *Clinical investigation plan (CIP)* - *临床调查计划（CIP）* - *Clinical investigation report (CIR)* - *临床调查报告（CIR）* - *Ethics committee approval(s)* - *伦理委员会批准* - *Competent Authority approval(s)* - *主管当局批准* - *Competent/Regulatory Authority correspondence (from all countries, including outside of EU)* - *主管/监管当局的通信（来自所有国家，包括欧盟以外）* - *Proof of public registration of study* - *公共注册研究的证明* - *Publications in scientific journals (if applicable)* - *在科学期刊上发表的文章（如适用）*	
	Outcome of the Clinical evaluation consultation/ notification **临床评估咨询/通知的结果** (class III implantable devices/class IIb active devices intended to administer and/or remove a medicinal product) (MDR Article 61, #2) （用于管理和/或移除药用产品的 III 类植入式器械/IIb 类有源器械） （MDR 第 61 条，#2）		*Documentation related to the consultation of the expert panel with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation and the outcome of the consultation with the expert panel* *与专家组协商相关的文件，旨在评审制造商的预期临床开发策略和临床调查建议，以及与专家组协商的结果* *Reference, where in the clinical evaluation due consideration of the views expressed by the expert panel can be found* *参考，在临床评估中能够找到对专家组所表达意见的适当考虑*	

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Article 32 **第32条**	**Summary of Safety and Clinical Performance (SSCP)** 安全性和临床性能总结（SSCP） Note: SSCP for implant-table devices and class III 注意：用于植入式器械和III类器械的SSCP		*Please follow the guidance laid down in **MDCG 2019-9**: Summary of safety and clinical performance* *请遵循 **MDCG 2019-9** 中规定制定的指南：安全性和临床性能总结*	
Post market surveillance (18) **上市后监管 (18)**				
Article 84 **第 84 条**	**PMS plan** **PMS计划**		*Refer to Annex III, #1.1* *参阅附录三，#1.1*	
6.1. (d)	**Post-market clinical follow-up plan and evaluation report (update of clinical evaluation)** **上市后临床跟踪计划及评估报告（临床评估更新）**		*Please refer to MDR, Annex XIV , Part B* *请参阅 MDR，附录十四，B 部分* *Documents expected as part of the PMS/PMCF documentation:* *PMS/PMCF 文档中的部分文件：* - *PMCF plan (including CIP of planned PMCF studies)* - *PMCF 计划（包括计划 PMCF 研究的 CIP）* - *PMCF report (where relevant)* - *PMCF 报告（如相关）* *Please follow the guidance laid down in:* *请遵循以下指南：* ***MDCG 2020-7** Guidance on PMCF plan template* ***MDCG 2020-7** PMCF计划模板指南* ***MDCG 2020-8** Guidance on PMCF evaluation report template* ***MDCG 2020-8** PMCF评估报告模板指南* *If PMCF is not considered applicable, this has to be duly justified.* *如果认为PMCF不适用，则必须有正当理由。*	
Article 86 **第 86 条**	**Periodic Safety Update Report** (PSUR) 定期安全性更新报告（PSUR） Note: PSUR for class IIa, IIb , III 注：IIa、IIb、III类的PSUR		*Please follow the guidance laid down in the respective MDCG document, as soon as available* *请尽快遵循相应 MDCG 文件中制定的指南*	
EU Declaration of Conformity (19) **欧盟符合性声明（19）**				
Annex IV **附录四**	**EC Declaration of Conformity** **欧盟符合性声明**		*Please ensure that the (draft) declaration of conformity (DoC) contains all information as outlined in MDR, Annex IV.* *请确保（草案）符合性声明（DoC）包含 MDR 附录四中概述的所有信息。* *For initial reviews or new products, a draft DoC is required.*	

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			对于首次评审或新产品，应提供一份草案 DoC。 *For TD reviews of existing products, please provide the related signed copy of the DoC.* *对于现有产品的 TD 评审，请提供相关签署的 DoC 副本。*	