The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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MDR Certification Process (including Pre-application, Application and Post Application phases) – Consensus document

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欧洲医疗器械认证机构协会

NB团队立场文件

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MDR 认证流程（包括申请前、申请及申请后阶段）——共识文件

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The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Purpose and Scope

The purpose of this consensus document is to describe in detail the pre-application, application processes through which manufacturers may apply to Notified Bodies (NBs) for the certification of medical devices under the regulation (EU) 2017/745 (MDR). The document was developed by reviewing the application process and associated documents of individual Team-NB members and harmonising the processes where possible. This document is applicable to both legacy devices (pursuant to Article 120) transitioning to MDR, and devices that are new to the market and have not been certified under the Directives before.

The document also briefly describes the certification activities that are undertaken after the application process is concluded.

This consensus guidance document is aligned to the requirements of Medical Devices Regulation [MDR] (EU) 2017/745, described in detail in Annex VII §4.2, §4.3 for pre-application and application requirements.

The following are outside the scope of this document:

- Application process for a NB certificate as per Article 16 of MDR.
- Application process for a NB opinion for devices as per Article 117 of MDR.
- Application process for Recertification as per Annex VII §4.11 of MDR.
- Conformity assessments according to Annex X + XI (B)

General Considerations

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a study (contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG) "Study supporting the monitoring of availability of medical devices on the EU market"[1]. The dashboard related to the study (as of Feb 2024) on the availability of devices indicates that it takes between 1-3 months to conclude the application process (from application to the conclusion of the written agreement) for majority of the applications under MDR. It is anticipated that providing a description of the application process with the steps involved in it, identification of the minimum/typical information/data required to be submitted by the manufacturers as part of the application process, will establish a common understanding and minimise the number of incomplete submissions received by the NBs. This will allow the NBs to process the applications more efficiently in a shorter time frame. While every effort has been made to harmonise the type and extent of documents/information requested during the application process across all NBs, each Notified Body reserves the right to request additional information from the manufacturer and may do so, to satisfy their specific operational processes. Any such additional information should be clearly defined in a formal document and published on the specific Notified Body's website.

[1] Study supporting the monitoring of availability of medical devices on the EU market

欧洲医疗器械认证机构协会

NB团队立场文件

目的与范围

本共识文件旨在详细阐述制造商根据（EU）2017/745号法规（MDR）向认证机构（NBs）申请医疗器械认证的预申请及申请流程。该文件通过审阅各团队认证机构成员的申请流程及相关文件，并在可行范围内统一相关流程而制定。本文件既适用于依据第120条从旧版法规过渡至MDR 的医疗器械，也适用于市场上新上市且此前未按相关指令获得认证的医疗器械。

该文件还简要描述了申请流程结束后开展的认证活动。

本共识指导文件符合《医疗器械法规[MDR]（欧盟）2017/745》的要求，相关要求在附件V第4.2节和第4.3节中对申请前及申请阶段的具体要求均有详细阐述。

以下内容不在本文件的范围内：

- 根据 MDR 第16条申请NB证书的流程。
- 根据 MDR 第117条，针对医疗器械申请NB意见的流程。
- 根据 MDR 附件VII第4.11条规定的再认证申请流程。
- 根据附件X和XI(B)进行的符合性评估

一般注意事项

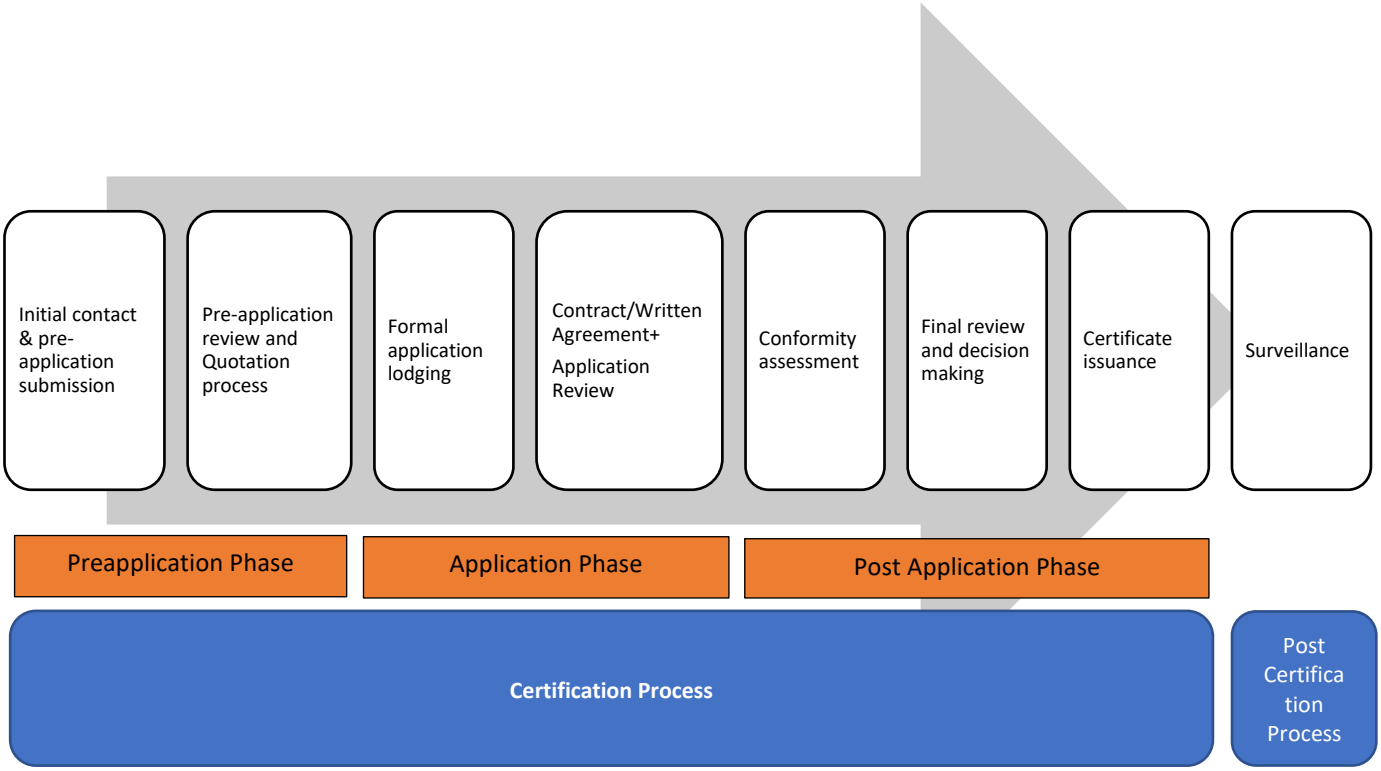
欧盟委员会健康与食品安全总司（DG SANTE）通过欧洲健康与数字执行机构（HaDEA），委托了一项研究（由奥地利国家公共卫生研究所（Gesundheit Osterreich GmbH/GOG）牵头的联合体承担）——《支持监测欧盟市场医疗器械可获得性的研究》[1]。该研究相关的数据仪表板（截至2024年2月）显示，针对 MDR 法规下的大多数申请，从提交申请到完成书面协议签署的整个审批流程耗时1至3个月。预计通过详细说明申请流程的具体步骤，并明确制造商在申请过程中需提交的最低/典型信息/数据要求，将有助于建立共识并减少监管机构收到的不完整申请数量，从而使监管机构能够更高效地缩短处理时间。尽管已尽一切努力使所有认证机构（NB）在申请过程中要求提供的文件/信息类型及范围保持一致，但各认证机构均有权根据其特定操作流程要求制造商提供额外信息。此类额外信息均应以正式文件形式明确界定，并发布于相应认证机构的官方网站上。

[1] 支持监测欧盟市场医疗器械可获得性的研究

This document is subject to future revisions as NBs gain further experience under MDR and to adapt it to changes in the regulation, development of other related guidance documents (e.g., MDCG documents) and any change in interpretation of the requirements over time.

Stages of the Certification Process:

The process below depicts the application and the overall certification process at a high level.



Initial contact & pre-application submission:

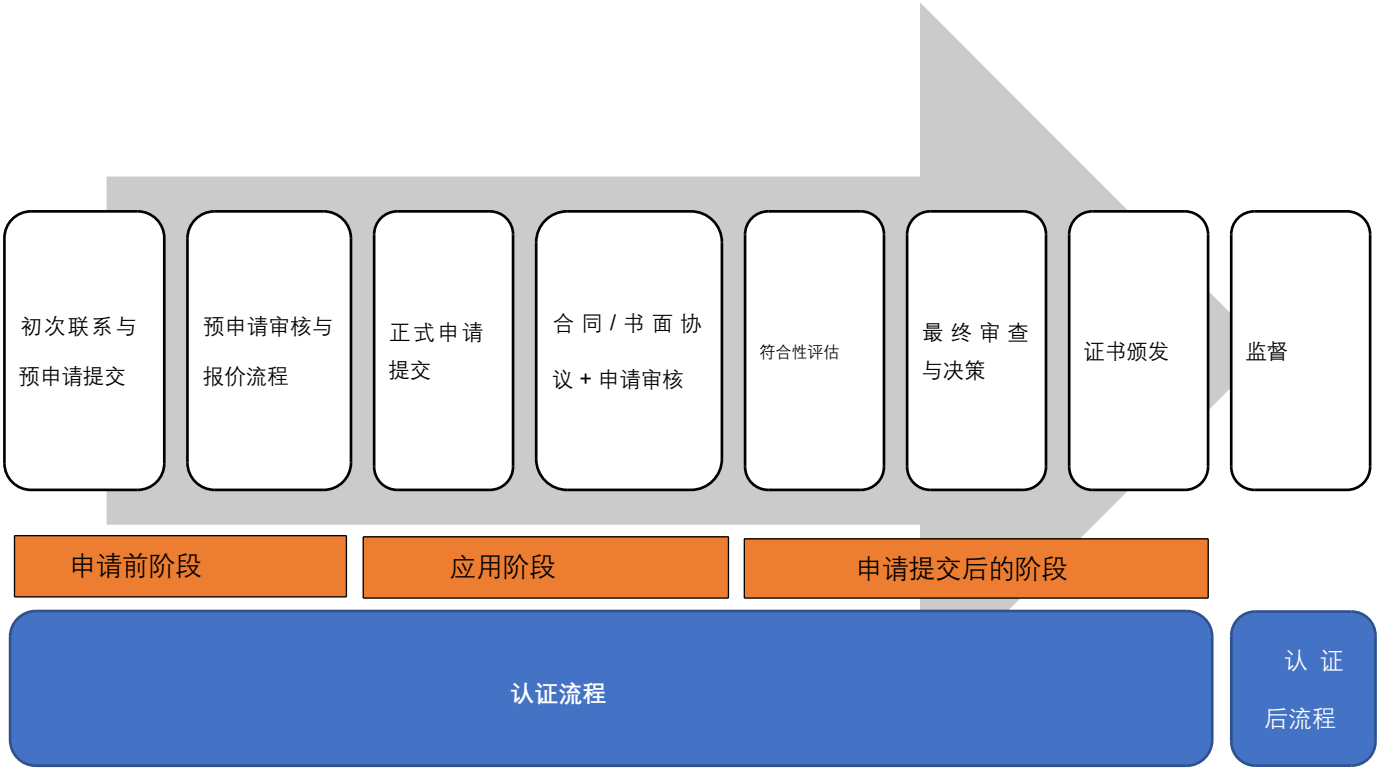
It is the first contact between a manufacturer and the NB regarding the provision of NB conformity assessment services for the manufacturer's product(s). The contact could be verbal or digital (emails, submission of web forms published on NB websites) requesting conformity assessment services from the NB. As per Annex VII §4.2 (d) of MDR, NBs are required to have in place "procedures requiring the review of pre-application information, including the preliminary verification that the product is covered by this Regulation and its classification, prior to issuing any quotation to the manufacturer relating to a specific conformity assessment". Pursuant to this requirement, NBs will request that the manufacturer or their EU Authorized Representative (EU Rep) submits information specified in Annex A of this document, to enable the preparation of a quotation for the conformity assessment services, to be provided by the NB.

It is important that manufacturers provide all the requested information and in sufficient detail to minimise any time spent on the requests for missing information and also for the NB to provide an accurate quotation for their services.

本文件将根据以下情况进行后续修订：随着NBs在 MDR 框架下积累更多经验；根据法规变化、其他相关指导文件（如 MDCG 文件）的制定进展；以及随时间推移对要求解释的任何调整。

认证流程的各个阶段：

下述流程从宏观层面展示了该应用程序及整体认证流程。



初次联系及预申请提交：

这是制造商与国家委员会（NB）就为其产品提供符合性评估服务事宜进行的首次沟通。此类沟通可通过口头或电子方式（电子邮件、提交发布于NB网站的在线表格）进行，旨在向NB申请符合性评估服务。根据 MDR 附件V第4.2(d)条的规定，NB必须建立“在向制造商出具特定符合性评估服务报价前，需审查申请前信息（包括初步确认该产品属于本法规适用范围及其分类）的相关程序”。基于此要求，NB将要求制造商或其欧盟授权代表（EU Rep）提交本文件附件A所列信息，以便编制由NB提供的符合性评估服务报价单。

制造商必须提供所有要求提供的信息，并且细节充分，以最大限度减少因缺失信息而产生的处理时间；同时，NB也需为其服务提供准确的报价。

Pre-application review and Quotation process:

The Pre-application information submitted by the Manufacturer or their EU Rep is reviewed by the NB as described in Annex VII §4.2 (d) of MDR for a preliminary verification that the products included in the pre-application are covered by the scope of MDR and their classification is accurate. Based on the information submitted about the manufacturer like their sites, subcontractors/suppliers, products etc the NB will provide a quotation to the manufacturer/EU Rep with the cost estimates for the conformity assessment services. The NB may request additional information or clarifications to enable the provision of an accurate quotation.

This quotation can be modified (with agreement from the manufacturer) at a later stage (during the application review or subsequent stages of conformity assessment) if the pre-application information provided has changed or if additional information becomes available that may impact the quotation originally provided.

Some NBs may also attach the contract template and the terms and conditions of contract along with the quotation, while other NBs provide these documents after the full submission of the application documents as explained below.

Formal application lodging

If the manufacturer is satisfied with the quotation provided by the NB and intends to proceed with the application process, they should, at a minimum, submit the following information to the NB:

- Documentation as per Annex IX § 2.1 or Annex XI Part A §6.1 for the assessment of the Quality Management System. Some NBs may have supplementary checklist to aid the submission of these documents.
- For Class III devices, and Class IIb devices that require a product certification, documentation as per Annex IX Section Chapter II §4.2.

The NB requires specific information for all devices covered by the application, including the intended purpose, qualification as a medical device, and classification - along with appropriate justification where these are not self-evident.

All the above-mentioned documentation should be accompanied by a form (if the NB has one), or a letter (“formal application”) signed by an authorized person of the Manufacturer or the Authorised Representative.

In cases where the manufacturer was already provided with the contract template and the terms and conditions of contract along with the quotation, the manufacturer may choose to provide the signed contract along with the application documents.

Refer to Appendix A and B of this document for the list of the data/documents required at this stage.

预申请审核及报价流程:

制造商或其欧盟代表提交的预申请信息将由NB按照 MDR 附件VII第4.2(d)节的规定进行审核，以初步验证预申请中包含的产品是否属于 MDR 适用范围且分类准确。根据所提交的制造商相关信息（包括其生产基地、分包商/供应商及产品详情等），NB将向制造商/欧盟代表提供符合性评估服务的成本估算报价。NB可要求补充信息或作出澄清，以确保报价的准确性。

若提供的申请前信息发生变化，或出现可能影响最初报价的额外信息，在后续阶段（如申请审查期间或符合性评估的后续环节）经制造商同意后，可对本报价进行修改。

部分NB机构可在报价单中一并附上合同模板及合同条款与条件；而其他NB机构则需待申请文件全部提交后（具体说明如下）再提供这些文件。

正式申请提交

若制造商对NB提供的报价单表示满意并拟继续推进申请流程，则至少应向NB提交以下信息:

- 根据附件IX第2.1节或附件XI第A部分第6.1节的要求编制文件，用于质量管理体系的评估。部分国家指南（NB）可能提供补充检查清单以协助提交这些文件。
- 对于III类医疗器械以及需要产品认证的IIb类医疗器械，应按照附件IX第II章第4.2节的要求提供相关文件。

《医疗器械法规》（NB）要求对应用程序涵盖的所有器械提供特定信息，包括预期用途、医疗器械认证资质及分类等级——若上述信息不明显，则需附上相应的说明依据。

上述所有文件均应附有表格（如NB文件中包含此类表格）或由制造商或授权代表的授权人员签署的信函（“正式申请书”）。

若制造商已收到合同模板、合同条款及条件以及报价单，则可选择同时提供已签署的合同及申请文件。

本阶段所需数据/文件清单详见本文件附录A和附录B。

Note: For legacy devices transitioning to MDR, [following the guidance in the Q&A document related to EU 2023/607][2] the MDR application does not need to include the full technical documentation to be submitted for the devices covered by the application. However, a plan for the submission of the technical documentation and sufficient information about the devices for the NB to verify the qualification of the products as devices, their respective classification, and the chosen conformity assessment procedure. The NB may need additional information about the legacy devices transitioning to MDR, where applicable, such as the device(s) intended to substitute a 'legacy device'. The information submitted with the application needs to allow the NB to issue an accurate quotation and complete the application review process.

Contract/Written Agreement and Application review

Once the application is lodged, if not already provided, the NB will provide the manufacturer, contract documents including the terms and conditions of the contract that cover all the elements as per the second subparagraph of Annex VII §4.3 of MDR. Once both the parties sign the contract, a written agreement is in place. The NB then proceeds with the application review process based on the documentation provided by the manufacturer.

Application review by the NB, as a minimum, includes the following elements (as per Annex VII §4.3 a-e of MDR):

(a) check the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, as referred to in the corresponding Annex, under which approval has been sought,
(b) the verification of the qualification of products covered by those applications based on the information collected,
(c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation,
(d) the ability of the notified body to assess the application based on its designation,
(e) the availability of sufficient and appropriate resources.

Based on the application review, the NB will decide whether to accept the application or refuse the application. Any refusals are notified in EUDAMED. Similarly, if the manufacturer decides to withdraw its application at this stage, the NB is obliged to notify the withdrawal via EUDAMED.

If a manufacturer wishes to add a new product to the application that was not a part of the original applications and related written agreement, the NB may request a new application to be lodged for the new products. If a manufacturer wishes to make changes to an application already submitted to the NB, they should contact the NB to discuss those changes are permissible, the process to submit those changes, and any impact to the existing application.

[2] https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a_1.pdf

注：对于向 MDR 过渡的旧有设备，[2]根据欧盟2023/607号指令相关问答文件中的指导要求，MDR 申请无需提交所涉设备所需的全部技术文档。但申请人需制定技术文档提交方案，并提供足够的设备信息供国家委员会（NB）核实产品作为医疗器械的资格认定、相应分类及选定的符合性评估程序。在适用情况下，国家委员会可能还需获取关于向 MDR 过渡的旧有设备的补充信息（例如拟替代“旧有设备”的具体器械）。随申请材料提交的信息必须确保国家委员会能够出具准确报价并完成申请审核流程。

合同/书面协议及申请审查

申请提交后（若制造商尚未提供），NB将向其提供合同文件，其中包含涵盖 MDR 附件V第4.3条第二款所规定所有要素的合同条款与条件。双方签署合同后，即形成书面协议。随后，NB将根据制造商提供的文件开展申请审查工作。

国家委员会（NB）对申请的审查至少应包含以下要素（依据 MDR 附件V第4.3节ae项规定）：

(a) 根据相应附件中所述的相关符合性评估程序要求，核查这些申请材料的完整性；该程序正是申请批准所依据的流程。

(b) 根据所收集的信息，对这些申请涵盖的产品资质进行验证。

(c) 申请人所选择的符合性评估程序是否适用于本法规所述相关器械。

(d) 公告机构根据其指定资格对申请进行评估的能力

(e) 充足且合适的资源的可获得性。

根据申请审查结果，NB将决定是否接受该申请。所有拒绝决定均通过eudamed系统通知。同样，若制造商在此阶段决定撤回其申请，NB有义务通过eudamed系统通知撤回事宜。

若制造商希望将原申请文件及相关书面协议中未包含的新产品纳入申报范围，国家生物制品监督管理局（NB）可要求针对该新产品另行提交新的申请文件。若制造商需对已提交给NB的申请文件进行修改，应联系NB以确认修改内容是否可行、修改提交的具体流程以及对现有申请可能产生的影响。

[2] https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a_1.pdf

Conformity assessment

Following the acceptance of the formal application and the conclusion of the written agreement, the NB conducts application review and draws up a plan to conduct the appropriate conformity assessment activities for each project including where applicable the physical, laboratory or other tests to be carried out. The choice of conformity assessment activities carried out is dependent on the classification of the device and the chosen conformity assessment procedure. The NB informs the manufacturer of the period during which the required conformity assessment activities are planned to take place. Typical conformity assessment activities required for various classifications are described below:

Class I Devices:

Class I devices do not require NB conformity assessments except in specific cases as described below.

Class I medical devices with a measuring function, Class I devices that are placed on the market in a sterile condition and Class I reusable surgical instruments are subject to NB conformity assessment. However, for these types of devices the intervention of the NB is limited to:

- the metrological aspects for class I devices with a measuring function,
- the aspects related to establishing, securing and maintenance of the sterile conditions for Class I devices placed on the market in a sterile condition, and
- the aspects related to the reuse of the device (cleaning, disinfection, sterilization, maintenance and functional testing and related instructions for use)

For the above class I devices, a stand-alone Technical Documentation assessment is typically not conducted. However, parts of Technical Documentation relevant to sterilization / metrology / re-use aspects as outlined above may be audited as part of audit activities.

Class IIa, IIb and Class III devices:

Class IIa, Class IIb and Class III devices require a combination of quality management system (QMS) audits, technical documentation assessments and testing of devices based on the chosen route to conformity. In addition to these activities, specific additional procedures/processes such as consultations with authorities may be required to be undertaken depending on the nature of the devices.

For QMS assessment, an audit is performed on the premises of the manufacturer, and if necessary, on the premises of the manufacturers' supplier(s) and subcontractor(s). The NB determines according to its audit rules and procedures if the manufacturer's quality management system meets the requirements of the regulation. If one or more devices included in the application are sterile, some NBs may undertake separate microbiology audits instead of covering those elements in the QMS audits. NBs issue a QMS audit report at the end of the audit documenting their findings including a recommendation for certification (or refusal) based on the findings. If any findings are characterised as major non-conformances, these would typically have to be fully addressed by the manufacturer in

符合性评估

在正式申请获得受理且书面协议签署后，国家机构（NB）将对申请进行审查，并针对每个项目制定相应的符合性评估方案，包括适用时需开展的物理检测、实验室测试或其他相关检测。所采用的符合性评估活动取决于医疗器械的分类及选定的评估程序。国家机构会向制造商明确计划实施所需符合性评估活动的具体时间范围。下文列出了不同分类医疗器械所需的典型符合性评估活动：

I类医疗器械：

I类医疗器械除下文所述特定情况外，均无需进行NB符合性评估。

具有测量功能的I类医疗器械、以无菌状态投放市场的I类器械以及可重复使用的I类外科手术器械均需接受国家生物医学实验室（NB）的符合性评估。然而，对于此类器械，NB的干预范围仅限于：

- 具有测量功能的I类设备的计量学要求
- 与确保以无菌状态投放市场的I类医疗器械的无菌条件建立、维持及保障相关的各项内容；
- 与该设备重复使用相关的各个方面（清洁、消毒、灭菌、维护、功能测试及相关使用说明）

对于上述I类器械，通常无需单独进行技术文件评估。然而，与上述灭菌/计量/重复使用相关的技术文件部分内容可作为审计活动的一部分进行审核。

IIa类、IIb类及III类医疗器械：

IIa类、IIb类及III类医疗器械需结合质量管理体系（QMS）审核、技术文件评估以及基于所选符合性路径的器械检测。除上述活动外，根据器械特性的不同，可能还需执行特定的附加程序/流程（如与监管机构进行咨询）。

针对质量管理体系（QMS）评估，需在制造商现场开展审核；必要时还需在其供应商及分包商的场所进行审核。认证机构（NB）依据自身的审核规则与程序，判定制造商的质量管理体系是否符合法规要求。若申请中涉及的一种或多种器械属于无菌产品，则部分认证机构可单独开展微生物学专项审核，而非将其纳入QMS审核范围。审核结束时，认证机构将出具QMS审核报告，详细记录审核结果，并据此提出认证批准或拒绝建议。若发现任何重大不符合项，制造商通常必须对此进行全面整改。

a timely manner and verified by the NB in an additional audit before a recommendation for certification can be made.

The technical documentation of the devices is assessed by the NB for compliance to the requirements specified in Annex II, Annex III of MDR as below:

- systematically for each class III device, and class IIb implantable device except those that are well established technologies (WET) such as pins, screws etc as specified in article 52(4) of MDR
- On a sampling basis for Class IIb WET, class IIb non implantable and class IIa medical devices. The NBs follow sampling guidelines as described in MDCG 2019-13. Clarification on sampling will be given by NB upon request.

It is important to note that it is a requirement for the NBs to take into consideration any applicable Common Specifications, MDCG guidance, best practice documents and harmonised standards in their assessments, even if the manufacturer does not claim to comply to them as per Annex VII §4.5.1. For instance, if a manufacturer chose an internal testing method to demonstrate compliance with a specific general safety and performance requirement instead of the use of a relevant harmonized standard, the NB may ask the manufacturer to provide a justification for the approach taken.

The NB may involve several experts in the assessment of technical documentation to ensure that technical documentation assessment is carried out by staff that have the relevant expertise in the areas they are assessing. This could include, but is not limited to a microbiologist, a clinician, a statistician, a toxicologist, a medicinal product expert, an animal/human derivative expert, a software expert etc.

NBs issue a technical documentation assessment report (TDAR) and a clinical evaluation assessment report (CEAR) documenting the outcomes of their assessment, any findings and a recommendation for certification (or refusal) based on the findings. Depending on the assessment model adopted by the NB, the gaps in compliance to the requirements maybe documented as non-conformities. The manufacturer must provide a Corrective and Preventive Action Plan (CAPA) and act with due diligence to address the non-conformities. Depending on the nature, severity and complexity of the findings and the actions to be taken, additional audits/assessments may be required before a recommendation for certification is made by the NB. In addition to the audit activities, the technical documentation assessments have to be completed with a positive result before the product reviewers can recommend the manufacturer for certification under MDR.

If the chosen conformity assessment route includes either Annex X (Type Examination) or Annex XI Part B (Product Verification), then additional testing of devices is carried out by the NB as per the requirements of the applicable annex.

Specific procedures

In addition to the QMS audits, technical documentation assessments and testing described above, one or more procedures described below may apply based on the classification of the devices and other functions/features of the device.

Note: The table below is limited to brief summaries of the applicable procedures. The applicable legislative references are included in the summaries which provide additional details on the procedures.

须及时完成，并经NB在额外审计中核实后，方可提出认证建议。

NB会对设备的技术文档进行评估，以确认其符合 MDR 附件II和附件III中规定的要求，具体如下：

- 针对所有III类医疗器械及IIb类植入式器械均需系统性评估，但已成熟技术（WET）产品（如针头、螺钉等）除外，具体要求参见 MDR 第52条第(4)款。
- 针对IIb类湿式医疗器械、非植入式IIb类医疗器械及IIa类医疗器械，均采用抽样评估方式。相关规范遵循 MDCG 2019-13中规定的抽样指南；如有需要，认证机构可提供抽样操作的具体说明。

需特别注意的是，认证机构（NB）在评估过程中必须考虑所有适用的通用规范、 MDCG 指南、最佳实践文件及协调标准，即使制造商未根据附件V第4.5.1节声明其符合这些要求。例如，若制造商选择采用内部测试方法而非相关协调标准来证明符合特定通用安全与性能要求，则认证机构可要求其说明所采用方法的理由。

国家委员会（NB）可邀请多位专家参与技术文件的评估工作，以确保评估工作由具备相关专业领域专业知识的人员完成。这些专家包括但不限于微生物学家、临床医师、统计学家、毒理学家、药品专家、动物/人类衍生物专家、软件专家等。

国家认证机构（NB）将出具技术文件评估报告（TDAR）和临床评价评估报告（CEAR），其中详细记录评估结果、相关发现以及基于这些发现提出的认证批准或拒绝建议。根据国家认证机构采用的评估模型，不符合要求的情况可被记录为不合格项。制造商必须制定纠正与预防措施计划（CAPA），并尽职履行职责以解决这些不合格项。根据发现情况的性质、严重程度及复杂性以及需采取的措施，在国家认证机构作出认证建议前可能还需进行额外审核或评估。除审核工作外，技术文件评估也须取得合格结果，产品评审人员方可依据 MDR 法规向制造商推荐认证申请。

若所选符合性评估途径包含附录X（型式检验）或附录XI第B部分（产品验证），则医疗器械的额外检测应由国家机构（NB）根据相应附录的要求进行。

具体操作流程

除上述质量管理体系（QMS）审核、技术文件评估及测试外，根据器械的分类及其其他功能/特性，还可适用以下一项或多项程序。

注：下表仅包含适用程序的简要概述。相关立法参考文献已纳入概述中，以提供关于这些程序的详细信息。

Type of device	Additional procedure
Class III implantable devices; and Class IIb active devices intended to administer or remove medicinal substances under rule 12	The clinical evaluation consultation procedure (CECP) as per Annex IX Section 5.1 of the MDR applies for these types of devices. For this procedure, the NB sends the clinical evaluation report to the Expert Panels appointed by the European Commission along with the manufacturer's clinical evaluation and other relevant documents. The expert panel decides within a specified timeline after receipt, whether it will issue a scientific opinion on the assessment of the clinical evaluation by the NB. If a scientific opinion is issued, the NB duly takes into account the expert panel opinion in its own certification decision making process.
Devices incorporating a medicinal substance	NB conducts a consultation procedure with a competent authority of a member state or the European Medicines Agency (EMA) in accordance with Annex IX, Section 5.2 of the MDR. If the substance falls under the scope of Directive (EC) No. 726/2004, then the consultation procedure must be conducted with the European Medicines Agency (EMA). In this procedure, a scientific assessment on the quality and safety of the medicinal substance, including the benefit and risk of use of the substance in the medical device, is obtained from the competent authority or EMA. The NB is required to submit manufacturer's medicinal dossier and the NB assessment of usefulness for the ancillary medicine to the medicinal product authority. The dossier is expected to follow Pharmaceutical (CTD) format. For submissions where a MDD certificate (and a consultation) has already been issued a declaration as per MDCG 2020-12 is required with respect to changes. The medicinal products authority consulted shall provide its opinion to the notified body within specified timeline after receipt of all the necessary documentation. When deciding whether to grant a certificate, NB takes due account of this scientific opinion and inform the competent authority consulted of its decision. If the assessment is unfavourable, NB may not issue the certificate. Where significant changes are made that impact the quality safety or usefulness of the ancillary substance, the notified body seeks the opinion of the medicinal products authority consulted, in order to confirm that the quality and safety of the ancillary substance remain unchanged. The NB may not deliver the supplement to the EU technical documentation assessment certificate if the scientific

设备类型	附加程序
III类可植入装置；以及根据第12条规则设计用于给药或撤药的IIb类主动装置	根据 MDR 附件IX第5.1节的规定，此类医疗器械均需遵循临床评估咨询程序（CECP）。该程序中，国家生物制品监管机构（NB）需将临床评估报告连同制造商提供的临床评估文件及其他相关资料一并提交给欧盟委员会指定的专家小组。专家小组在收到材料后规定时限内，将就NB的临床评估结果出具科学意见。若出具科学意见，NB应在认证决策过程中充分考虑该专家小组的意见。
含有药物成分的装置	NB应根据 MDR 附件IX第5.2节的规定，与成员国主管机构或欧洲药品管理局（EMA）开展咨询程序。若该物质属于指令(EC)第726/2004号的适用范围，则必须向欧洲药品管理局（EMA）进行咨询。 在此流程中，需从主管机构或欧洲药品管理局（EMA）获取关于药物物质质量与安全性的科学评估报告，该评估涵盖该物质在医疗器械中的使用益处及风险。 国家生物制品监管机构（NB）须向药品监管部门提交生产商提供的药品档案资料以及对该辅助药物适用性的评估报告。该档案资料应遵循《药品技术文档》（CTD）格式。对于已获得 MDD 证书及咨询意见的申报材料，若存在变更，则需按照 MDCG 2020-12条款提交变更声明。 受咨询的药品监管机构应在收到所有必要文件后，在规定时限内向公告机构提供其意见。 在决定是否颁发证书时，NB应充分考虑该科学意见，并将决策结果告知所咨询的主管部门。若评估结果不利，则NB不得颁发该证书。 当对辅料的质量、安全性或实用性作出显著变更时，公告机构应征求所咨询的药品监管机构的意见，以确认辅料的质量和安全性保持不变。若缺乏科学依据，公告机构不得颁发欧盟技术文件评估证书。

Type of device	Additional procedure
	opinion provided by the medicinal products authority consulted is unfavourable. The notified body shall convey its final decision to the medicinal products authority consulted.
Devices utilizing non-viable human derivatives.	NB conducts a consultation with a human tissues and cells Competent Authority as per Directive 2004/23/EC. The NB submits a summary of the preliminary conformity assessment which provides, among other things, information about the non-viability of the human tissues or cells in question, their donation, procurement and testing and the risk or benefit of the incorporation of the tissues or cells of human origin or their derivatives into the device. Within specified timelines after receipt of all the necessary documentation, the human tissues and cells competent authority shall provide to the NB its opinion. When deciding whether to grant a certificate, NB takes due account of this scientific opinion and inform the competent authority consulted of its decision. If the assessment is unfavourable, NB may not issue the certificate. Before any change is made with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing or procurement, the manufacturer shall inform the notified body of the intended changes. The NB consults the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained. The NB may not deliver a supplement to the EU technical documentation assessment certificate if the scientific opinion is unfavourable and conveys its final decision to the human tissues and cells competent authority concerned.
Devices utilizing non-viable animal tissue/cells/ derivatives	If a product is manufactured using tissue or derivatives from animal tissue of certain species in accordance with Regulation (EU) No. 722/2012, then NB conducts a consultation procedure as specified in said regulation. After its assessment, NB issues a "Summary Evaluation Report" (SER) which is forwarded via the coordinating Competent Authority to the competent authorities of all member states. Should the member states have comments, then these are considered, and appropriate corrective actions initiated by the NB. NB duly takes into account the scientific opinion in its decision on the granting or extension of a certification.
Devices that are composed of substances or of	For devices, or their products of metabolism, which are systemically absorbed by the human body in order to achieve their intended purpose, NB conducts a consultation procedure as per Annex IX

设备类型	附加程序
	所咨询的药品监管机构提供的意见不具支持性。公告机构应将其最终决定传达给该咨询过的药品监管机构。
采用非活体人类来源衍生物的装置。	NB根据欧盟指令2004/23/EC的要求，与人体组织及细胞主管部门进行了咨询。 国家委员会（NB）应提交初步符合性评估摘要，其中除其他内容外，需包含所涉人体组织或细胞的不可用性、其捐献、获取及检测情况，以及将人源组织/细胞或其衍生物纳入该器械所带来的风险或获益信息。在收到所有必要文件后的规定时限内，主管人体组织与细胞管理机构应向国家委员会提供其评估意见。 在决定是否颁发证书时，NB应充分考虑该科学意见，并将决策结果告知所咨询的主管部门。若评估结果不利，则NB不得颁发该证书。 在对植入器械的人源非活性组织或细胞及其衍生物（特别是涉及其捐赠、检测或获取方面）进行任何变更前，制造商必须将拟议变更通知公告机构。该机构应咨询参与初始磋商的相关主管部门，以确认植入器械中的人源组织或细胞及其衍生物的质量与安全性得以保持。 若科学意见不具支持性且已向相关人体组织与细胞主管部门传达最终决定，则NB可能不会向欧盟技术文件评估证书提供补充材料。
采用非活体动物组织/细胞/衍生物的装置	若某产品根据欧盟第722/2012号法规使用特定物种动物组织或其衍生物制成，则欧盟委员会（NB）将按照该法规规定的程序开展咨询程序。经评估后，欧盟委员会将出具《总结性评估报告》（SER），并通过协调主管机构向所有成员国的主管部门发送。若成员国提出意见，则欧盟委员会将予以考虑并采取相应的纠正措施。 NB在决定是否授予或延长认证时，应充分考虑科学意见。
由特定物质构成的装置	对于那些为实现预期用途而被人体全身吸收的器械或其代谢产物，NB均依据附件IX开展咨询程序。

Type of device	Additional procedure
combinations of substances that are absorbed by or locally dispersed in the human body (Rule 21)	Section 5.4 of the MDR together with a competent authority as per Directive 2001/83/EC or the European Medicines Agency (EMA). In this procedure, a scientific opinion is issued as to whether the applicable requirements specified in Annex I of Directive 2001/83/EC are adhered to with the product. The manufacturer provides the required data in the scope and format stipulated by the respective authority. NB duly takes into account this scientific opinion in its decision on the granting or extension of the certification and informs the consulted authority of its decision.

Systems and procedure packs as per Article 22(3) of MDR:
In the case of systems and procedure packs intended to be placed on the market according to article 22(3) of MDR, the procedures and the involvement of the notified body is limited to aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged.
Class III custom-made implantable devices:
In the case of class III custom-made implantable devices, the involvement of the Notified Body is limited to assessment of the quality management system established by the manufacturer to comply with the applicable requirements. This is typically undertaken by the NB in the form of QMS audits as described in the section above for Class IIa, IIb and Class III devices.

Final review and decision making

Once the required conformity assessment activities are complete, the NB carries out the final review and decision-making steps to either issue a certificate or refuse certification based on the outcomes and recommendations of the assessment activities carried out. This review is carried out by personnel who have not been involved in the conformity assessment procedure for the devices concerned.
The final review process verifies that:

- the reports and supporting documentation for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application, and
- there are no unresolved non-conformities preventing issuance of a certificate.

The favourable or unfavourable results of this review are typically reflected in an internal report and acts as a summary containing the main stages of the certification process, the outcomes of the assessments and concludes by giving a recommendation for whether or not to issue the certificate as part of decision-making process by the appropriate personnel of the Notified Body.

The decision-making process takes into the account the recommendations from the final review step, the assessment document and other relevant additional information available to decide whether the requirements of the MDR have been fulfilled and hence issue a certificate or refuse certification. The decision-making step, amongst other things, also considers the adequacy of the post-market surveillance plan, including the PMCF plan, any specific milestones that need to be set for further

设备类型	附加程序
合作　　关于..... *被.....吸收的物质* *或在人体内局部分布（规则21）*	根据指令2001/83/EC或欧洲药品管理局（EMA）的要求， MDR第5.4节规定需与主管机构共同开展评估。在此程序中，将出具科学意见，确认产品是否符合指令2001/83/EC附件I所规定的适用要求。制造商须按照相关主管部门规定的范围和格式提交所需数据。 NB在决定是否授予或延长认证时应充分考虑该科学意见，并将决策结果告知相关主管部门。

根据 MDR 第22条第(3)款规定的系统及程序包：
对于根据 MDR 第22条第3款拟投放市场的系统及操作规程包，相关操作流程及认证机构的参与范围仅限于确保无菌包装在开启或损坏前保持无菌状态的相关环节。

III类定制可植入装置：
对于III类定制式可植入器械，认证机构的参与仅限于评估制造商建立的质量管理体系是否符合相关要求。此项工作通常由认证机构通过质量管理体系审核（QMS audit）形式开展，具体实施方式如上文针对IIa类、IIb类及III类器械所述。

最终审查与决策

完成所需的符合性评估活动后，国家机构（NB）将根据所开展评估活动的结果与建议，进行最终审查并作出是否颁发证书或拒绝认证的决定。此项审查由未参与相关医疗器械符合性评估流程的人员执行。最终审查过程旨在验证以下内容：

- 用于决策的报告及支持文件（包括针对评估过程中发现的不符合项处理方案）在应用范围方面均完整且充分。
- 不存在任何未解决的不符合项，因此不会影响证书的签发。

本次审查的有利或不利结果通常会体现在内部报告中，该报告作为摘要概述了认证流程的主要阶段、评估结果，并最终提出是否颁发证书的建议，供公告机构的相关人员在决策过程中参考。

决策过程综合考虑最终审查阶段的建议、评估文件及其他可用的相关补充信息，以判定是否满足 MDR 要求，从而决定是否颁发证书或拒绝认证。该决策环节还重点评估上市后监测计划（包括 PMCF 方案）的充分性以及需设定的具体实施里程碑。

review by the notified body of the up-to-date clinical evaluation, any specific conditions or provisions that need to be defined for the certification, and the period of certification without exceeding five years.

Certificate Issuance:

If the decision-making process concludes with a decision to issue the certificate, the NB then generates the certificate(s) as per the applicable routes to conformity containing information specified in Annex XII of MDR.

The certificates are released to the manufacturer and submitted to the EUDAMED system (mandatory as per the timelines specified in EU 2023/1860).

Surveillance activities

Prior to the initial certification, the NB plans the surveillance activities required to maintain the certificates issued. The NB keeps up to date a surveillance program that includes annual QMS audits at the legal manufacturer, and their subcontractors/suppliers if relevant, assessment of PSURs, validation of SSCPs, technical documentation assessments on a sampling basis for Class IIa, Class IIb devices excluding Class IIb implantable non-WET devices, assessment of vigilance data and unannounced audits. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly.

Surveillance audits

A surveillance QMS audit is performed at least every 12 months at the legal manufacturer to ensure that the manufacturer is maintaining the certified Quality Management System. The surveillance activities may include physical, laboratory or other tests either carried out by the NB or witnessed by the NB while the manufacturer undertakes those tests. In addition to the audits at the manufacturer, audits may be conducted at the subcontractors/suppliers in duly justified cases.

Technical documentation sampling

For class IIa and certain IIb medical devices, the NB will prepare a technical documentation assessment sampling plan as per the guidance in MDCG 2019-13 to ensure annual technical documentation assessments of a representative device(s) from the groups initially certified.

Unannounced audits

Unannounced audits are conducted at least once every five years. The audit may take place at the manufacturer sites or at the premises of their subcontractors/suppliers.

Vigilance reports

It is mandatory for the manufacturers to submit copies of their device vigilance reports to their NB. The NB is required to assess the vigilance data and take appropriate actions such as for-cause audits,

由指定机构对最新的临床评估结果、认证所需明确的具体条件或条款以及不超过五年的认证有效期进行审核。

证书颁发日期:

若决策过程最终决定签发证书，NB则根据 MDR 附件XII中规定的符合性判定适用流程及所需信息生成相应证书。

相关证书需提交给制造商并上传至eudamed系统（根据欧盟法规EU 2023/1860规定的时限要求，此步骤为强制性）。

监控活动

在初次认证之前，国家认可机构（NB）需规划为维持已颁发证书所需的监督活动。NB应持续更新监督计划，内容包括：对法定制造商及其相关分包商/供应商（如适用）进行年度质量管理体系审核；评估产品安全更新报告（PSUR）；验证安全关键部件（SSCP）；针对IIa类和IIb类医疗器械（不包括IIb类可植入非湿式器械）按抽样方式开展技术文件评估；分析警戒数据；以及实施突击审核。在进行此类现场审核时，指定机构应在必要时开展或要求进行检测，以确保质量管理体系正常运行。

监督审计

应在法定制造商处至少每12个月开展一次质量管理体系（QMS）监督审核，以确保制造商持续维护经认证的质量管理体系。监督活动可包括由国家机构（NB）实施或在制造商进行测试期间由国家机构见证的物理检测、实验室检测或其他相关测试。除对制造商进行审核外，在确有正当理由的情况下，还可对分包商/供应商开展审核。

技术文件抽样

对于IIa类及部分IIb类医疗器械，NB将依据 MDCG 2019-13中的指南制定技术文件评估抽样方案，以确保对初始认证组别中的代表性器械进行年度技术文件评估。

未通知的审计

未事先通知的审计至少每五年进行一次。审计可在制造商现场或其分包商/供应商的场所进行。

警戒报告

制造商必须向其国家监管机构（NB）提交设备警戒报告副本。国家监管机构有义务评估这些警戒数据并采取相应措施，例如开展专项审计。

document reviews, or updating the technical documentation sampling plan to change the order of devices sampled etc., including determining any impact on the certificates issued.

Periodic Safety Update Reports

Manufacturers are required to prepare Periodic Safety Update Reports (PSURs) for Class III, Class IIb and Class IIa devices at the frequency specified in Article 86 of MDR. The PSURs for class III devices, and implantable devices of other classifications are required to be submitted to their NB without undue delay. The NB is required to evaluate these reports and take appropriate actions if any concerns are noted in the data.

Substantial changes

Manufacturers are required to have a process in place to notify the NB of any plans for substantial changes to their quality management system or the devices. The notification requirements are based on the conformity assessment route followed. The NB is required to assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of the MDR, and notify the manufacturer of its decision. Depending on the nature of the change, the NB may have to conduct additional conformity assessment activities such as QMS audits or technical documentation assessments to support the approval of the change.

Language:

Language of Technical Documentation
(Requirements *to be specified by NB*).

Language of QMS Documentation
(Requirements to be specified by NB).

包括文件审查、更新技术文档中的采样计划以变更所采样器械的顺序等，并评估这些变更对已签发证书可能产生的影响。

定期安全更新报告

制造商须按照 MDR 第86条规定的频率，为III类、IIb类及IIa类医疗器械编制定期安全性更新报告（PSUR）。针对III类器械及其他类别植入式器械的PSUR必须及时提交至其国家生物医学产品委员会（NB）。该委员会需对这些报告进行评估；若数据中存在任何疑点，则应采取相应措施。

重大变更

制造商必须建立相应流程，以便向国家生物医学产品管理局（NB）通报其质量管理体系或医疗器械的重大变更计划。通知要求取决于所采用的符合性评估途径。NB需对拟议变更进行评估，并验证变更实施后，质量管理体系、器械设计或器械类型是否仍符合 MDR 的要求，并将决策结果告知制造商。根据变更性质的不同，NB可能还需开展额外的符合性评估活动（如质量管理体系审核或技术文件评估），以支持变更获批。

语言:

技术文档的语言
（具体要求由NB规定）。

质量管理体系文件的语言
（具体要求由NB方规定）。

Appendix A: List of customer master data to be submitted to the notified body and kept up to date

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
Applicant Legal Manufacturer facility EUDAMED: FLD-ACT-004 = MFActorType **(repeat for all other facilities; other facilities are typically not covered by EUDAMED)**	Company name including legal form, website (if any) and (if applicable) name and legal form of the mother company	FLD-EUD-023	X	
	Registered Company Number (Business Registration Number) and VAT number	FLD-EUD-032		X
	Street and Number	FLD-EUD-034 and 035	X	
	ZIP Code	FLD-EUD-039	X	
	City	FLD-EUD-036	X	
	Country	FLD-EUD-042	X	
	Headcount (FTEs involved in medical device(s) related activities	-	X	
	Applicable shifts and details of the shifts	-	X	

附录A：需提交至公告机构并保持更新的客户主数据清单

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
申请人法定制造商设施 已批准：FLD-ACT-004 = MFactorType **（适用于所有其他设施；其他设施通常不包含在eudam-ed范围内）**	公司名称（含法律形式）、网站（如有）以及（如适用）母公司名称及法律形式	FLD-EUD-023	X	
	注册公司编号（企业登记号）及增值税号	FLD-EUD-032		X
	街道名称及门牌号	FLD-EUD-034；以及035	X	
	ZIP 代码	FLD-EUD-039	X	
	城市	FLD-EUD-036	X	
	国家	FLD-EUD-042	X	
	参与医疗器械相关活动的人员数量（按全职当量计算）	-	X	
	适用的班次及班次详情	-	X	

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
	Seasonal variations and opening and closing time	-		X
	Activities/processes conducted at this site	-	X	
	Primary contact person Remark: contain details shall contain name, phone number and email	FLD-EUD-026	X	
	SRN	FLD-ACT-001	X	
	Person Responsible for Regulatory Compliance (PRRC)	FLD-ACT-006	X	
Authorized Representative EUDAMED: FLD-ACT-004 = ARActorType Remark: the Authorized Representative can also be listed as Supplier.	Company name including legal form	FLD-EUD-023	X	
	Street and Number	FLD-EUD-034 and 035	X	
	ZIP Code	FLD-EUD-039	X	
	City	FLD-EUD-036	X	

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
	季节变化及营业时间	-		X
	在该地点开展的各项活动/流程	-	X	
	主要联系人 备注：详细信息应包含姓名、电话号码及电子邮箱。	FLD-EUD-026	X	
	SRN	FLD-ACT-001	X	
	合规监管负责人（PRRC）	FLD-ACT-006	X	
授权代表 EUDAMED: FLD-ACT-004 = ARActorType 备注：授权代表亦可列为供应商。	公司名称（包括法律形式）	FLD-EUD-023	X	
	街道名称及门牌号	FLD-EUD-034；以及 035	X	
	ZIP 代码	FLD-EUD-039	X	
	城市	FLD-EUD-036	X	

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
	Country	FLD-EUD-042	X	
	Primary contact person	FLD-ACT-006 or FLD-ACT-049	X	
	SRN	FLD-ACT-001	X	
(per) Supplier(s) (This information is usually not required for all suppliers but for suppliers having a relevant influence on the conformity of the devices, also termed as "Crucial suppliers and/or Critical subcontractors")	Company name including legal form	-[1]	X	
	Street and Number	-[1]	X	
	ZIP Code	-[1]	X	
	City	-[1]	X	
	Country	-[1]	X	
	Provided services	-	X	
	Certification/accreditation information (including certificates)	-	X	
	Details on manufacturer's control over supplier (this includes but is not	-		X

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
	国家	FLD-EUD-042	X	
	主要联系人	FLD-ACT-006 或; FLD-ACT-049	X	
	SRN	FLD-ACT-001	X	
（按）供应商 （该信息通常并非对所有供应商均必需，仅对那些对医疗器械符合性具有重要影响的供应商（亦称为“关键供应商和/或关键分包商”）才需提供。）	公司名称（包括法律形式）	[1]	X	
	街道名称及门牌号	[1]	X	
	ZIP 代码	[1]	X	
	城市	[1]	X	
	国家	[1]	X	
	提供的服务	-	X	
	认证/认可信息（包括证书）	-	X	
	关于制造商对供应商控制权的详细信息（包括但不限于以下内容）	-		X

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
	limited to: quality agreement, supplier audits, incoming inspection, final tests)			
Devices	Name	FLD-UDID-22	X	
	Variants	Yes (as UDIs below a BUDI)	X	
	Basic UDI-DI Remark: in case the Basic UDI is unknown during pre-application please indicate which devices will have the same or different Basic UDI-DI	FLD-UDID-14	X	
	Identification as a "Medical device", "accessory", "procedure pack" or "System"	FLD-UDID-12[2]	X	
	Description of device including: • qualification as well establish technology • Mode of action	-	X	
	Intended Purpose	-	X	
	MD Codes (MDA, MDN, MDT, MDS)	-[3]	X	
	EMDN code	FLD-UDID-149	X	
	Classification (Include, additionally, applicable categories for class Ir devices)	FLD-UDID-16	X	

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
	仅限于：质量协议、供应商审核、进货检验、最终测试）			
设备	姓名	FLD-UDID-22	X	
	变体；版本	是的（正如.....） UDI值低于..... a BUDI)	X	
	基本UDI-DI 备注：若在申请前阶段无法确定基础UDI，请注明哪些设备将使用相同或不同的基础UDI-DI。	FLD-UDID-14	X	
	认定其为“医疗器械”、“附件”、“操作包”或“系统”	FLD-UDID-12[2]	X	
	设备描述包括: • 既具备资质，又拥有成熟技术 • 作用机制	-	X	
	预期用途	-	X	
	MD编码（MDA、 MDN 、MDT、MDS）	[3]	X	
	EMDN 代码	FLD-UDID-149	X	
	分类（另需包含Ir类设备适用的类别）	FLD-UDID-16	X	

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
	Classification rules applied	-	X	
	Explanation / remark concerning the classification / Rationale why the device is Medical Device, if necessary	-	X	
	Re-processing details (if any) Remark: please indicate if single-use devices are subject to re-processing.	-	X	
	Identify the device as configurable device (if applicable)	-		X
	Involved facilities and type of activity provided Note: this shall be a link to the already defined facilities; type of activity e.g. means design, manufacturing, sterilization, packaging etc.	-	X	
	Involved suppliers and type of service provided Note: this shall be a link to the already defined suppliers; type of service e.g. means design, manufacturing, sterilization, packaging etc.	-	X	
	Current Status of the device (e.g., covered by certificate, to be added)	-	X	
	Details of any novel feature	-		X
	CMR ED substances involved Note: Carcinogenic, Mutagenic, or toxic to Reproduction (CMR) substances and Endocrine Disrupting (ED) substances	-	X	

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
	已应用分类规则	-	X	
	关于分类的说明/备注 / 该器械为何属于医疗器械的依据（如适用）	-	X	
	再处理详情（如有）备注：请注明一次性使用器械是否需进行再处理。	-	X	
	将该设备识别为可配置设备（如适用）	-		X
	涉及的设施及提供的活动类型 注：该链接应指向已定义的设施；活动类型（例如：设计、制造、灭菌、包装等）。	-	X	
	参与的供应商及提供的服务类型 注：该链接应指向已定义的供应商；服务类型（例如：设计、制造、灭菌、包装等）。	-	X	
	该设备的当前状态（例如是否已获得认证证书等）	-	X	
	任何新功能的详细信息	-		X
	CMR 所含 ED 物质 注：具有致癌性、致突变性或对生殖系统有毒性（CMR） 物质及内分泌干扰（ED）物质	-	X	

Data group	Data item	EUDAMED field	Required for the first-time during pre-application	Required for the first time during formal Application
	Covered by certificate(s) Note: only needed in case one date set covers multiple certificates	-		X
Sterilization processes	Sterilization method Examples: EO, moist heat, gamma		X	
	Inhouse/outsourced	-	X	
	Details on the sterilization process Hint: this must include the sterilization process identification like cycle xyz	-		X
	Involved facilities Hint: this shall be a link to the already defined facilities	-	X	
	Involved suppliers Hint: this shall be a link to the already defined suppliers	-	X	

Remarks:

- The data requested during one phase can also be requested again during other phase for example data requested at the pre-application phase can also be requested again during the application phase for verification or conclusion. In the table above, a particular data item is mentioned under the phase where it is requested for the first time in the process.
- The data in the table above must be kept up to date and communicated to the notified body at suitable intervals.
- Changes to the data shall be covered by a change set as described in Appendix C
- [1]: importers are available in EUDAMED
- [2]: accessory is not covered by this field
- [3]: while the codes are part of ScopeType.xsd a relation to FLD-UDID was not found

数据组	数据项	欧达梅德场	必需 这是在申请前阶段首次发生的情况。	在正式申请过程中首次需要提交
	附有证书 注：仅当一个日期集涵盖多个证书时才需使用。	-		X
灭菌工艺	灭菌方法 示例：环氧乙烷（EO）、湿热、γ射线		X	
	内部开发/外包	-	X	
	灭菌过程详细信息提示：必须包含灭菌过程标识（如循环xyz）。	-		X
	相关设施 提示：此应为已定义设施的链接。	-	X	
	相关供应商 提示：该链接应指向已定义的供应商。	-	X	

备注：

- 在某一阶段请求的数据可在其他阶段再次获取；例如，在申请前阶段请求的数据亦可在申请阶段再次获取，以供验证或结论确认。上表中，每项数据均标注了其在整个流程中首次被请求的阶段。
- 上表中的数据必须保持最新，并按适当间隔向指定机构通报。
- 数据变更应纳入附录C所述的变更集范围内。

-[1]：eudamed中提供导入功能

-[2]：该配件不在本条款覆盖范围内

[3]：虽然这些代码属于ScopeType.xsd文件的一部分，但未发现其与FLD- UDID 之间的关联。

Appendix B: List of further documents and information to be submitted to the notified body

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
Conformity assessment Annex	Requested conformity assessment annex(es)	X	
Quality system Documentation	Evidence of business registration / Excerpt from the commercial register		X
	Parts of the quality management system as required by Annex IX 2.1 (or Annex XI Part A 6.1)		X
	Existing certifications	X	
	Audit language requirements	X	
Previous Applications	Details on previous application(s) for the same device-related quality management system or devices under this application Remark: this also includes applications which have not led to certification or final assessment by another Notified Body for CE	X	

附录B：需提交至公告机构的其他文件及信息清单

数据组	数据项	首次申请前需填写	在正式申请过程中首次需要提交
符合性评估附件	要求的符合性评估附件	X	
质量体系文件	企业注册证明/商业登记簿摘录		X
	根据附件IX第2.1条（或附件XI第A部分第6.1条）要求的质量管理体系组成部分		X
	现有认证	X	
	审计语言要求	X	
先前的应用程序	关于同一器械相关质量管理体系或本申请所涉器械的既往申请详情 注：此范围还包括尚未获得其他认证机构针对CE认证的认证或最终评估的应用产品。	X	

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
Technical documentation(s)	Technical documentation (see the remark below)		X
	Language of the technical documentation(s)	X	

Remarks:

- At the time of the application, instead of the full technical documentation for each and every device, the NB may find it acceptable to receive enough information about the devices to allow the notified body to verify the qualification of the products as devices, their respective classification and the chosen conformity assessment procedure including the drawing up of the conformity assessment program.

Appendix C: Change sets

The data provided in Appendix A shall not arise or change on its own. It shall be wrapped in a change set which can initiated by the manufacturer (client) or the notified body (CB/NB). The set needs to contain additional information allowing the other party (not submitting the change) to understand and handle the change.

Data item	Explanation	Required
Triggering party	Manufacturer or CB/NB	X
Identification	A unique identification of the change set	X
Contact person	Name, phone number and email of the contact person	X
Status	The status of this change set Examples: Draft | Waiting for client approval | Waiting for CB/NB approval | Needs correction by client | Needs correction by CB/NB | Finished	X

数据组	数据项	首次申请前需填写	在正式申请过程中首次需要提交
技术的文档（们）	技术文档（参见下方说明）		X
	技术文档的语言	X	

备注：

- 在提交申请时，除每种器械的完整技术文件外，认证机构（NB）可能认为接收足够的器械信息即可满足要求，以便其能够验证产品作为医疗器械的合格性、相应的分类以及所选择的符合性评估程序（包括制定符合性评估方案）。

附录C：变更集

附录A中提供的数据不得自行产生或变更。该数据应封装于变更集内，该变更集可由制造商（客户）或公告机构（CB/NB）发起。变更集需包含额外信息，以便另一方（未提交变更的一方）能够理解并处理该变更。

数据项	解释；说明	必需
触发方	制造商或CB/NB认证机构	X
识别；鉴定	对变化集的唯一标识	X
接触者	联系人的姓名、电话号码和电子邮件地址	X
状态	此变更集的状态 示例：草稿 | 等待客户批准 | 等待CB/NB批准 | 需客户修改 | 需CB/NB修改 | 已完成	X

Data item	Explanation	Required
Further data - in case of changes triggered by the manufacturer (client)	Data required by NBCG-MED PAPER ON PROCEDURES AND CRITERIA FOR NOTIFICATION OF CHANGES UNDER MDR AND IVDR	X
Description – in case of changes triggered by the CB/NB	A clear description of the modifications applied	

Note 1: Depending on the situation a change set needs to be approved by the other party. The approval process might require corrections.

Note2: Manufacturers and notified bodies shall be capable of handling overlapping change sets which need to be merged once approved/finished.

数据项	解释；说明	必需
其他数据——如因制造商（客户）变更所致	NBCG -MED文件中关于 MDR 与 IVDR 下变更通知程序及标准的要求数据	X
说明——如因CB/NB引发变更时	对所实施修改的清晰描述	

注1：根据具体情况，变更集需获得另一方批准。审批过程可能需要进行修改。

注2：制造商及认证机构应具备处理重叠变更集的能力，此类变更集需在获批/完成时予以合并。