Editor:	**Team-NB**	Adoption date	18/12/2024	Version 1

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

Contents

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.

General Considerations

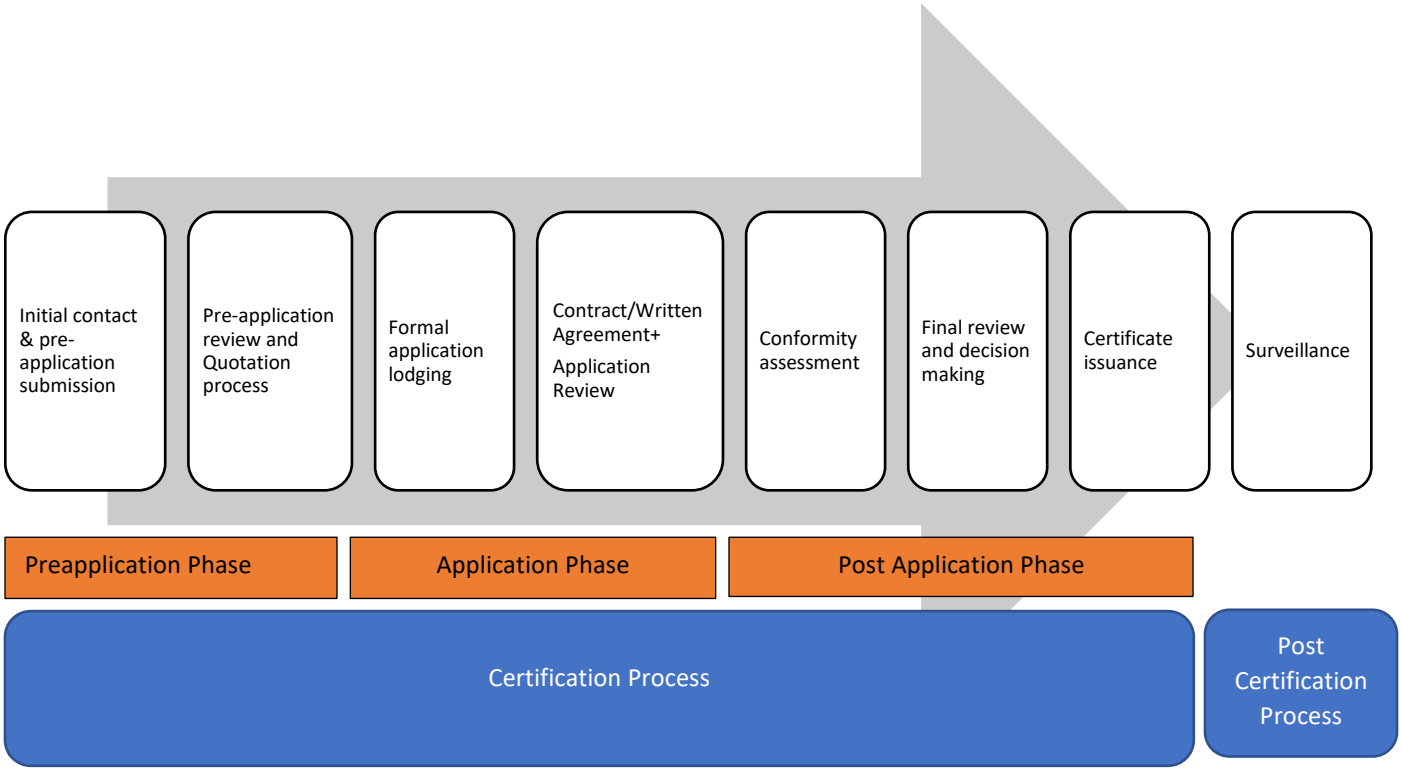
The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a study (contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG) "Study supporting 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.

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.

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

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.

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 NB's 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 annex certificate, documentation as per Annex IX Section Chapter II §4.2.

The NB may request full/sections/summary of technical documentation as part of the application to gather 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.

All the above-mentioned documentation should be accompanied by a form (if the NB has one), or a letter ("formal application") signed by the Manufacturer or its 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 of this document for the list of the data/documents required at this stage.

Note: For legacy devices transitioning to MDR, [following the guidance in the Q&A document related to EU 2023/607] 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 as devices and their respective classifications,
(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 (only after the signing of the contract). Any refusals are notified in EUDAMED or via alternative means (if EUDAMED is not being used). Similarly, if the manufacturer decides to withdraw its application at this stage, the NB is obliged to notify the withdrawal via EUDAMED or alternative means (if EUDAMED is not being used).

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.

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 barrier 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).

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 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.

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.

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.

Type of device	Additional procedure
	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 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

Type of device	Additional procedure
	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 combinations of substances that are absorbed by or locally dispersed in the human body (Rule 21)	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 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 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

At the conclusion of initial certification, the NB defines 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.

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.

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 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.

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, 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.

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.

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).

Appendix A: List of data/documents to be submitted by the manufacturer at various phases of the process

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
Applicant Legal Manufacturer facility (repeat for all other facilities)	Company name including legal form and website (if any)	X	
	Registered Company Number (Business Registration Number)		X
	Street and Number	X	
	ZIP Code	X	
	City	X	
	Country	X	
	Headcount (FTEs involved in medical device(s) related activities	X	
	Applicable shifts and details of the shifts	X	
	Seasonal variations and opening and closing time		X
	Activities/processes conducted at this site	X	
	Primary contact person	X	
	SRN	X	
	Person Responsible for Regulatory Compliance (PRRC)	X	
	Identification of various economic operators like legal manufacturer, importer, supplier, distributors etc.	X	
Conformity assessment Annex	Requested conformity assessment annex(es)	X	

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
Authorized Representative	Company name including legal form	X	
	Street and Number	X	
	ZIP Code	X	
	City	X	
	Country	X	
	Primary contact person	X	
	SRN	X	
(per) Supplier(s) (This information is usually not required for all suppliers but for suppliers having a relevant influence to the conformity of the devices, also termed as "Crucial suppliers and/or Critical subcontractors")	Company name including legal form	X	
	Street and Number	X	
	ZIP Code	X	
	City	X	
	Country	X	
	Provided services	X	
	Certification/accreditation information (including certificates)	X	
	Details on manufacturer's control over supplier (this includes but is not limited to: quality agreement, supplier audits, incoming inspection, final tests)		X
Devices	Name	X	
	Variants	X	
	Part Number	X	

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
	Basic UDI-DI	X	
	Remark: in case the Basic UDI is unknown during pre-application please indicate which devices will have the same or different Basic UDI-DI		
	Identification as a "Medical device", "accessory", "procedure pack" or "System"	X	
	Description of device including whether it qualifies for well establish technology or not and further details on the technology including details on whether device contains any components of animal or human origin or of substances, which may be considered medicinal products	X	
	Intended Purpose	X	
	EMDN code	X	
	Classification (Include, additionally, applicable categories for class Ir devices)	X	
	Classification rules applied	X	
	Explanation / remark concerning the classification / Rationale why the device is Medical Device, if necessary	X	
	Product without intended medical purpose according to MDR Annex XVI-additional details	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
	All facilities	X	

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
	Current Status of the device (e.g., covered by certificate, to be added)	X	
	Details of any novel feature		X
	If the device contains standalone/integrated software, specify the standalone software/firmware classification as per EN 62304. If the device incorporates Artificial Intelligence, indicate that.	X	
Sterilization processes	Sterilization method	X	
	Inhouse/outsourced	X	
	Details on the sterilization process		X
	Involved facilities	X	
	Involved suppliers	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
	Audit language requirements	X	
Previous Applications	Details on previous application(s) (that have not led to certification or final assessment by the Notified Body for CE) for the same device-related quality management system or devices under this application	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

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.
- 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.