Editor:	**Team-NB**	Adoption date	09/04/2025	Version 1

IVDR 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 in-vitro medical devices under the regulation (EU) 2017/746 (IVDR). 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 110) transitioning to IVDR, 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 In-Vitro Medical Devices Regulation [IVDR] (EU) 2017/746, 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 IVDR.

- Application process for Recertification as per Annex VII §4.11 of IVDR.

General Considerations

MDCG 2022-14 Action 16 encourages Notified Bodies (NBs) to develop common guidelines to assist manufacturers in the conformity assessment process. Several initiatives have already been undertaken by NBs, such as the development of the IVDR Technical Documentation Best Practice Guidance V.1.

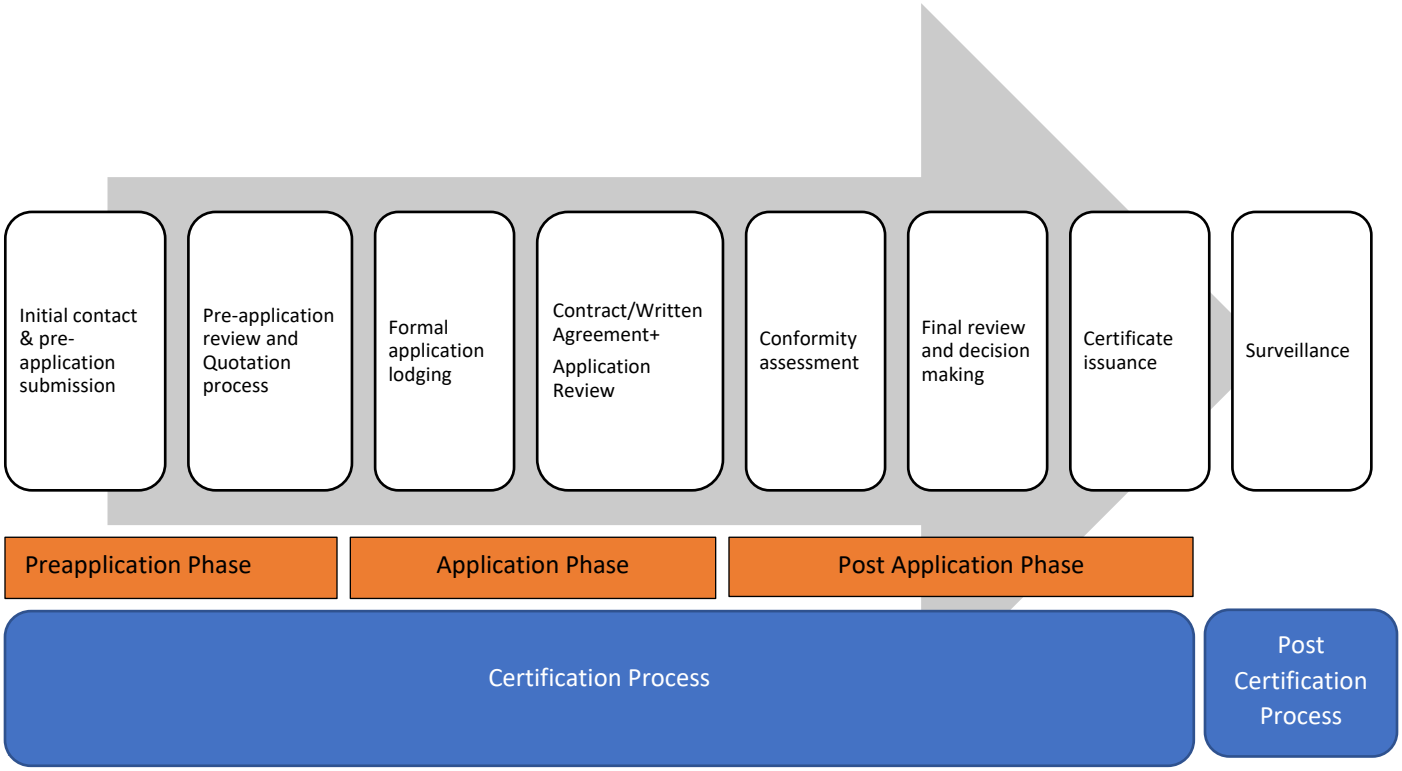
Similar to the previously published Team-NB Position Paper on the MDR Certification Process, this position paper aims to provide a detailed description of the application process, including the steps involved and the minimum/typical information and data required from manufacturers. This will help establish a common understanding and minimize the number of incomplete submissions received by 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 IVDR 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 IVDR, 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 (EC 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 EC Rep is reviewed by the NB as described in Annex VII §4.2 (d) of IVDR for a preliminary verification that the products included in the pre-application are covered by the scope of the IVDR and their classification is accurate. Based on the information submitted by the manufacturer like their sites, subcontractors/suppliers, products etc the NB will provide a quotation to the manufacturer/EC 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 accepts 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 §3.1 for the assessment of the Quality Management System. Some NBs may have supplementary checklist to aid the submission of these documents.
- For class B, C and D technical documentation as per Annex IX Chapter II §4.2.
- In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in per Annex IX chapter II, section § 5.1 (b).
- For Companion Diagnostics (CDx), the application shall include the documentation as per Annex IX Chapter II § 5.2 (b)
- Additional documentation may be required for Class D devices to comply with Implementing Regulation 2022/944 on task and criteria for European Reference Laboratories (EURL).

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 EC Rep.

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

Note: For legacy devices transitioning to IVDR, [following the guidance in the Q&A document related to EU 2024/1860] the IVDR 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 IVDR, 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 IVDR. 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 IVDR):

(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 functional).

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 product. If a manufacturer wishes to make changes to an application already submitted to the NB, they should contact the NB to discuss whether those changes are allowed 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 develops 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 A Devices:

Class A devices do not require NB conformity assessments except if they are placed on the market in sterile conditions.
For Class A devices placed on the market in sterile conditions, the intervention of the NB is limited to the audit of aspects related to establishing, securing and maintaining sterile conditions.

Class B, C and Class D devices:

Class B, Class C and Class D devices require a combination of quality management system (QMS) audits, technical documentation assessments (TDA)and testing of devices based on the chosen route to conformity. In addition to these assessments, specific additional procedures/processes such as consultations with authorities may be required to be undertaken depending on the nature of the devices. Certain Class D devices may need expert involvement as per Article 48 (6) of the IVDR for assessing the manufacturer's performance evaluation report (PECP). If designated, European Reference Laboratories (EURLs) must verify the manufacturer's performance claims and compliance with relevant standards according to Article 48(5). In addition, as per article 50 (1) after a certificate for a class D device is granted, the notified body shall notify competent authorities via Eudamed (when functional) or via the EU Commission platform CIRCABC until Eudamed is functional.

Companion Diagnostics (CDx) devices also require consultation with a competent authority designated by Member States under Directive 2001/83/EC or the EMA. More details on these procedures are provided in the "Specific Procedures" section below.

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 if the manufacturer's QMS 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 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 IVDR as below:

- for each class D device, Companion Diagnostics (CDx) and devices for self-testing or near-patient testing
- On a sampling basis for Class B and Class C devices for professional use (with the exception of devices for near-patient testing). 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 technical 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 performance evaluation assessment report (PEAR) documenting the outcomes of their assessment (sometimes these are combined in one report) and those of external consultations, 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 Annex X (Type Examination), then additional testing of devices is carried out by the NB as per the requirements of the 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 include a brief summary of the applicable procedures. The applicable legislative references, which provide additional details on the procedures, are included below .

Type of device	**Additional procedure**
Class D devices	For performance verification (IVDR Art. 48(5) and Annex IX 4.9 or Annex X 3 (j)) of class D devices which fall in scope of the designated EU Reference Laboratories (EURLs), two scenarios can be encountered: 1. For all class D devices for which a formal application is lodged with the notified body from 1 October 2024, the NB is obliged to contact appropriate EURLs to engage in consultation activities regarding the performance verification of class D device. During the conformity assessment, the NB requests one of the EURLs to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable CS, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent (IVDR Annex IX 4.9/Annex X 3(j). Laboratory tests performed by an EURL in particular focuses on analytical and diagnostic sensitivity using the best available reference materials. The EURL provides a scientific opinion within 60 days. The NB may not provide the manufacturer with the EU Technical Documentation Assessment certificate if the scientific opinion of the EU reference laboratory is unfavourable. 2. For class D devices for which a formal application was lodged before the 01 October 2024, the performance verification will be conducted before renewal. For class D devices that do not fall in the scope of the designated EURLs, the NBs may still decide to conduct physical, laboratory or other tests in accordance with Annex IX Sections 3.4 and 4.3/ Anne X Section 3 (f) and (g).

Type of device	Additional procedure
Class D devices where no CS are available and where it is also the first certification for that type of device	The performance evaluation consultation procedure (PECP) as per Article 48(6) and Annex IX Section 5.1/Annex X 3(j) of the IVDR applies for this type of devices. For this procedure, the NB sends the Performance evaluation report (PER) (according to the Eudamed document D5.1 it is encouraged to also include the most updated version of the instruction for use) provided by the manufacturer to the Expert Panel appointed by the European Commission within five days from receiving it. Due to the stringent deadline for submitting the PER to the expert panel, the NB will forward the PER without conducting a detailed assessment. Additionally, the expert panel consultation is a one-way process, meaning no additional information can be submitted afterward. Consequently, it is imperative that the PER is as comprehensive as possible. The expert panel provides within 60 calendar days after receipt, a scientific view on the performance evaluation report. The NB duly takes into account the expert panel view in its own certification decision making process.
Verification of manufactured class D devices-test plan	For Class D devices, during the Performance Evaluation phase of the conformity assessment, whether the Performance Verification activities are performed by a designated EURL or solely by the NB via alternative means (when a EURL is not designated for a specific category of devices or the IVDR application has been submitted after the 1st October 2024), batch criteria need to established in order for the batch test plan to be set up to allow the batch verification activities that follow the issuance of the certificate.
Class D-Changes	Where significant changes are planned that impact the performance and/or the intended use the notified body will assess the planned changes and decide if further assessment is required and potentially EURL needs to be consulted
Companion Diagnostics devices	NB initiates 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/Annex X (k) of the IVDR. If the medicinal 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 opinion on the suitability of the device in relation to the medicinal product concerned, is delivered from the competent authority or EMA. The NB is required to submit the device draft Instructions for Use (IFU) and draft Summary of Safety and performance (SSP) to the national medicinal product authorities or to the European Medicines Agency (EMA) in accordance with Annex IX, Chapter II section 5.2/Annex X (k). .

Type of device	Additional procedure
	In addition, the NB is expected to provide an "intention-to-submit-letter" to the EMA at least 3 months before the planned submission date of request for a scientific opinion. Further details on the consultation process are available in the following EMA 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. Where significant changes are planned that impact the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product, the notified body will assess the planned changes and decide whether a new conformity assessment according to article 48 is required or if the issuance of a supplement to the EU technical documentation assessment certificate is sufficient. In the latter case, the NB seeks the opinion of the medicinal products authority consulted, in order to confirm the suitability of the device with the medicinal product. The medicinal products authority consulted shall give its opinion within 30 days of receipt of the all the necessary documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (f) of Section 5.1.

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 account the recommendations from the final review step, the assessment documents and other relevant additional information available to decide whether the requirements of the IVDR 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 PMPF plan and any specific milestones that need to be set for further review, if required, or specific conditions and provisions that need to be defined for the certification.

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 IVDR.
The certificates are issued and uploaded on the EUDAMED system once fully functional

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 SSPs, technical documentation assessments on a sampling basis for Class B and Class C devices, assessment of vigilance data and unannounced audits.

A surveillance QMS audit is performed at least once every 12 months at the legal manufacturer to ensure that the manufacturer is maintaining the certified QMS. 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 where appropriate.

For class B and class C devices for professional use, 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 or categories initially certified.

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

It is mandatory for the manufacturers to submit copies of their device vigilance reports to their NB as per article 84(2) of the IVDR 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) and Summary of Safety and Performance (SSP) for Class D and Class C devices at the frequency specified in Article 81 and Article 29 of IVDR. The PSURs for class D devices, are required to be submitted to their NB at least annually. The

NB is required to evaluate these reports and take appropriate actions if any concerns are noted in the data.
For class C devices, the NB verifies the PSUR for at least one device for which it has issued EU Certification. This verification can be performed during periodic surveillance of EU QMS certificate and EU TDA renewal activities.
The SSP must be validated by the NB involved in the conformity assessment and made available to the public via EUDAMED. The validated SSPs are registered in EUDAMED by the NB, in general during the issued certificate registration, and kept up to date in EUDAMED (if functional).

Manufacturers are required to have a process in place to notify the NB of any plans for substantial changes to their QMS 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 QMS, or the design of a device or type of a device, still meets the requirements of the IVDR, 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.

6.3.3. Batch Verification of manufactured class D device

The NB is responsible for verifying batches of manufactured Class D IVDs (IVDR Art. 48 & Annex VII 4.5.3). This verification is based on a review of the manufacturer's QC release data and the batch test plan established during the conformity assessment, including any findings from the EURL (if available).

To verify the conformity of manufactured Class D devices, the manufacturer must conduct tests on each batch of devices (QC release). Upon completing these controls and tests, the manufacturer promptly forwards the relevant reports to the NB. Additionally, the manufacturer provides samples of the manufactured batches to the EURL (if designated). The EURL then performs its own testing and informs the NB of its findings.

The NB documents the outcome of its assessment of the manufacturer's data and the EURL’s findings (if available). The NB communicates the decision of batch approval or rejection to the manufacturer within 30 calendar days of receiving the samples. Following this verification procedure, manufacturers may place Class D IVDs on the market unless the NB notifies the manufacturer of any other decision within the agreed timeframe.

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	
	(Application for)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	

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
	Part Number	X	
	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 an "IVD Medical device", "accessory", "kit" or "System"	X	
	Description of device 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 and IVDR codes	X	
	Classification	X	
	Classification rules applied	X	
	Explanation / remark concerning the classification / Rationale why the device is IVD Medical Device, if necessary	X	
	Identify the device as configurable/variant device (if applicable)		X
	All facilities	X	
	Current Status of the device (e.g., covered by certificate, to be added)	X	
	Details of any novel feature		X

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
	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 3.1)		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	
Technical documentation(s)	Expected date of Technical documentation submission (see the remark below)	X	X

Data group	Data item	Required for the first-time during pre-application	Required for the first time during formal Application
	Technical documentation submission (see the remark below)		

Remarks:

- The data requested during one phase can also be requested again during the following phase; for example data requested at the pre-application phase can also be requested again during the application phase for verification, conclusion and if specifically required by Annex VII 4.3. 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.