GUIDE

APPLICATION FOR CERTIFICATION UNDER REGULATION (EU) 2017/745

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GMED
LNE GROUP

TABLE OF CONTENTS

FOREWORD

This document describes how companies can apply to GMED for certification of their quality management system or medical devices in accordance with Regulation (EU) 2017/745 (MDR).

This guide explains how to obtain a quotation and submit a formal certification application to GMED.
It also specifies the certification activities carried out once the formal application for certification and the contract has been signed, as well as the decision-making and post-certification monitoring stages.

It is intended for :
- Device manufacturers or their authorised representatives;
- Distributors and importers involved in relabeling and repackaging of devices[1];
- Any natural or legal person who sterilizes systems or kits with a view to placing them on the market[2];
- Manufacturers of products combining drugs and devices[3].

The procedures for submitting a formal application for certification of quality management system and/or the devices you wish to place on the market are defined by Regulation (EU) 2017/745.

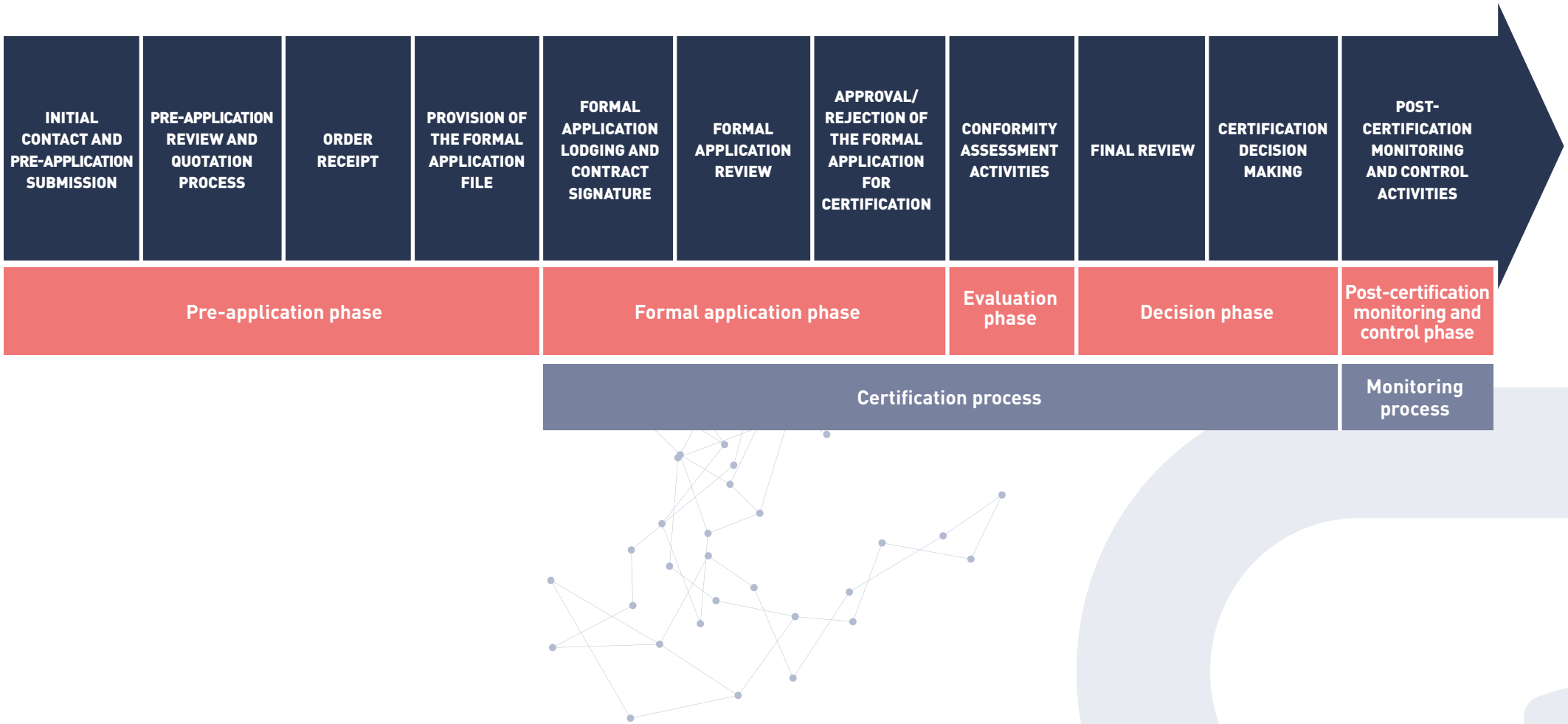
The documents you need to provide to submit your application, as well as the conformity assessment activities performed by GMED according to the conformity assessment procedure applicable to the class of your devices or activities, are detailed in section 4 of this guide.

GMED can offer its certification services under Regulation (EU) 2017/745 as part of its scope of designation (available under NANDO http://ec.europa.eu/growth/tools-databases/nando/).

For further information, please send your request to:
- request@lne-gmed.com (companies based in America);
- info@lne-gmed.com (companies based in rest of the word).

[1] *In accordance with article 16(2) of the MDR*
[2] *In accordance with article 22(3) of the MDR*
[3] *Within the meaning of article 1(8) and 1(9) of the MDR*

GMED CERTIFICATION PROCESS ACCORDING TO REGULATION (EU) 2017/745



II PRE-APPLICATION PHASE

2.1 → Contact and pre-application submission

In order to submit your certification project to GMED, we invite you to enter your information on our application GMED Connect.

New customers can request access to GMED Connect by contacting our business development department:

- By e-mail:
  - request@lne-gmed.com (companies based in America)
  - info@lne-gmed.com (companies based in rest of the word)
- By filling in the contact form on our website at the following address: https://lne-gmed.com/contact-offices

We ask you to fill in the information requested so that GMED can carry out, as soon as possible, the examination prior to submitting your formal application for certification and prepare a quotation for the conformity assessment services to be carried out.

All documents required as part of the formal application for certification (including technical documentation (TD)), as well as all correspondence, must be in GMED's working languages: English or French.
On-site audits are conducted in French or English.
GMED reports are written in English or French.

2.2 → Preliminary examination of request, issue of quotation and acceptance of order

The information entered in GMED Connect is analyzed by GMED to verify that the products and activities, where applicable, fall within the scope of the Regulations and that their classification is correct

On the basis of the information provided, GMED will send you an estimated quote for the specific conformity assessment. This quote can be modified during the assessment process, if necessary.

III FORMAL APPLICATION PHASE

On receipt of your order, GMED gives you access to your formal application for certification file from your GMED Connect space, and the associated certification contract is sent to you.

3.1 → Formal application for certification

To continue the certification process, you will need to submit a formal application for certification file. The content of this file varies according to your company's activities , class and type, as well as the specific features of the device and the conformity assessment procedure chosen.

When you submit your formal application, GMED will ask you to submit the documents required to gather the information needed to verify that the products are indeed medical devices, their classification and the conformity assessment procedure chosen.

The documents requested are an integral part of the formal application for certification file. They must be sent to GMED from GMED Connect in a format that allows them to be consulted and treated.

The formal application file includes generally :
- A section relating to the Quality Management System (QMS);
- A section relating to the device(s).

Depending on the conformity assessment procedure chosen, the above section(s) must be forwarded to GMED. The standard content of each section is detailed in paragraph 4.3 of this guide.

Additional information and documents to be provided within these sections, depending on the conformity assessment procedure chosen, are available in the sub-sections of paragraph 4.3 of this guide.

3.2 → Examination of the formal certification application and signature of the certification contract

Following submission of your formal application for certification file, GMED will review your formal application. If necessary, GMED can discuss with you to clarify certain points or complete your application file.

The purpose of the application review is to:
- Check the completeness of the formal application for certification with respect to the requirements of the relevant conformity assessment procedure chosen by the applicant;
- Validate the qualification of products as devices and their respective classifications;
- Confirm that the conformity assessment procedure chosen by the applicant is applicable to the device(s) in question under the MDR;
- Ensure GMED's ability to assess the formal application for certification based on its designation;
- Ensure the availability of sufficient and appropriate resources for conformity assessment activities.

Alongside your formal application for certification submission, you must return the signed certification contract.

3.3 → Acceptance/Rejection of formal application for certification

Following your formal application file review, GMED either accepts or rejects your formal application for certification.

Any rejection of a formal application for certification is notified in EUDAMED. Similarly, if you decide to withdraw your formal application for certification after submitting your formal application file, GMED is required to notify the withdrawal in EUDAMED.

If you wish to add new products or activities to the scope of your formal application for certification, these must be the subject of an update to your formal application for certification or of a new formal application for certification, as appropriate.

Updating or submitting a new formal application for certification is done via GMED Connect by following the modification process.

IV CONFORMITY ASSESSMENT PHASE

Following acceptance of your formal application and signature of the contract, GMED carries out the appropriate conformity assessment activities for each certification project.

Section 4.1 describes the conformity assessment activities to be carried out and the content of the formal application for certification to be submitted, depending on the conformity assessment procedure and the risk class of the device or activities carried out by your company.

4.1 → Conformity assessment procedures and activities

RISK CLASS AND DEVICE TYPE	CONFORMITY ASSESSMENT PROCEDURES	CONFORMITY ASSESSMENT ACTIVITIES			CONTENTS OF THE FORMAL APPLICATION FILE		
		TD ASSESSMENT	QMS AUDIT	OTHER	QMS (see section 4.3.1 of the guide)	DEVICE (see section 4.3.2 of the guide)	ADDITIONAL DOCUMENTS
III non-implantable or III implantable or IIb implantable	Annex IX Chapters I, II and III	Each device	Full	Testing if necessary	X	X	See section 4.3.3 of the guide
	Annex X + Annex XI - Part A	Each device	Limited to production	Testing on representative samples for each device	X	X	See section 4.3.6 of the guide
	Annex X + Annex XI - Part B	Each device	For sterile devices only: Limited to aspects relating to establishing, securing and maintaining sterile conditions.	Testing on each device[1]	NA	X	See section 4.3.7 of the guide
Custom-made III implantable	Annex IX Chapter I + Annex XIII	NA	Full	Testing if necessary	X	X	See section 4.3.11 of the guide
	Annex XI - Part A + Annex XIII	NA	Limited to production	Testing on representative samples for each device	X	X	See section 4.3.12 of the guide
IIb non-implantable or IIb implantable type WET[4] or IIb active intended to administer and/or remove a medicinal product from the body	Annex IX Chapters I and III	Sampling (1 device / generic group[2])	Full	NA	X	X	See section 4.3.4 of the guide
	Annex X + Appendix XI - Part A	Each device	Limited to production	Testing on representative samples for each device	X	X	See section 4.3.6 of the guide
	Annex X + Appendix XI - Part B	Each device	For sterile devices only: Limited to aspects relating to establishing, securing and maintaining sterile conditions.	Testing on each device[1]	NA	X	See section 4.3.7 of the guide

4.1 → Conformity assessment procedures and activities (afterpart)

RISK CLASS AND DEVICE TYPE	CONFORMITY ASSESSMENT PROCEDURES	CONFORMITY ASSESSMENT ACTIVITIES			CONTENTS OF THE FORMAL APPLICATION FILE		
		TD ASSESSMENT	QMS AUDIT	OTHER	QMS (see section 4.3.1 of the guide)	DEVICE (see section 4.3.2 of the guide)	ADDITIONAL DOCUMENTS
IIa or IIa implantable	Annex IX Chapters I and III	Sampling (1 device / category[3])	Full	NA	X	X	See section 4.3.4 of the guide
	Annex XI - Part A - Section 10 included	Sampling (1 device / category)	Limited to production	NA	X	X	See section 4.3.8 of the guide
	Annex XI - Part B - Section 18 included	Each	For sterile devices only: Limited to aspects relating to establishing, securing and maintaining sterile conditions.	Testing on each device[1]	NA	NA	See section 4.3.9 of the guide
Is (sterile)	Annex IX Chapters I and III	NA	Limited to aspects relating to establishing, securing and maintaining sterile conditions.	NA	X	NA	See section 4.3.5 of the guide
	Annex XI - Part A	NA	Limited to production for aspects relating to establishing, securing and maintaining sterile conditions.	NA	X	X	See section 4.3.10 of the guide
Im (measuring function)	Annex IX Chapters I and III	NA	Limited to aspects relating to the conformity of the devices with the metrological requirements	NA	X	NA	See section 4.3.5 of the guide
	Annex XI - Part A	NA	Limited to production for aspects relating to the conformity of the devices with the metrological requirements	NA	X	X	See section 4.3.10 of the guide
Ir (reusable surgical instruments)	Annex IX Chapters I and III	NA	Limited to aspects relating to the reuse of the device (cleaning, disinfection, sterilization, maintenance, functional testing, and the related instructions for use)	NA	X	NA	See section 4.3.5 of the guide
	Annex XI - Part A	NA	Limited to production for aspects related to the reuse of the device	NA	X	X	See section 4.3.10 of the guide

4.1 → Conformity assessment procedures and activities (afterpart)

RISK CLASS AND DEVICE TYPE	CONFORMITY ASSESSMENT PROCEDURES	CONFORMITY ASSESSMENT ACTIVITIES			CONTENTS OF THE FORMAL APPLICATION FILE		
		TD ASSESSMENT	QMS AUDIT	OTHER	QMS (see section 4.3.1 of the guide)	DEVICE (see section 4.3.2 of the guide)	ADDITIONAL DOCUMENTS
Isr (sterile and reusable)	Annex IX Chapters I and III	NA	Limited to aspects relating to establishing, securing and maintaining sterile conditions and aspects relating to the reuse of the device.	NA	X	NA	See section 4.3.5 of the guide
	Annex XI - Part A	NA	Limited to production for aspects relating to establishing, securing and maintaining sterile conditions and aspects relating to the reuse of the device.	NA	X	X	See section 4.3.10 of the guide
Ism (sterile and measurement function)	Annex IX Chapters I and III	NA	Limited to aspects relating to establishing, securing and maintaining sterile conditions and aspects relating to the conformity of the devices with the metrological requirements.	NA	X	NA	See section 4.3.5 of the guide
	Annex IX - Part A	NA	Limited to production for aspects relating to establishing, securing and maintaining sterile conditions and aspects relating to the conformity of the devices with the metrological requirements.	NA	X	X	See section 4.3.10 of the guide
Imr (measuring function and reusable)	Annex IX Chapters I and III	NA	Limited to aspects relating to the conformity with the metrological requirements and aspects relating to the reuse of the device.	NA	X	NA	See section 4.3.5 of the guide
	Annex IX - Part A	NA	Limited to production for aspects relating to the conformity with the metrological requirements and aspects relating to the reuse of the device.	NA	X	X	See section 4.3.10 of the guide
Article 1st section 8 and 9: Drug-device combination	Article 117	Conformity assessment of the device part of the drug-device combination (DCD) with the general safety and performance requirements of Annex I of the MDR.	NA	NA	NA	X	See section 4.3.13 of the guide

Table 1: Applicable conformity assessment procedures and activities according to risk class and device type

[1] *The tests do not apply to the manufacturing aspects of achieving sterility*
[2] *A generic device group corresponds to the 4th level of the EMDN nomenclature*
[3] *A device category corresponds to the MDA/MDN code*
[4] *Well-Established Technologies: suture, staple, dental filling, orthodontic appliance, dental crown, screw, wedge, plate, guide, pin, clip and connecting device*

4.1 → Conformity assessment procedures and activities (afterpart)

ACTIVITIES CARRIED OUT BY YOUR COMPANY	CONFORMITY ASSESSMENT PROCEDURES	CONFORMITY ASSESSMENT ACTIVITIES			CONTENTS OF THE FILEFORMAL APPLICATION		
		TD ASSESSMENT	QMS AUDIT	OTHER	QMS	DEVICES	ADDITIONAL DOCUMENTS
Article 22 § 3 Sterilization of systems or requirements with a view to placing them on the market	Annex IX Chapters I and III	NA	Limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	NA	X	NA	See section 4.3.5 of the guide
	Annex XI - Part A	NA	Limited to production for the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	NA	X	NA	See section 4.3.10 of the guide
Article 16 § 2.a Translation and/or relabeling of devices already on the market[1]	Article 16 § 4	NA	Limited to aspects relating to the conformity with requirements concerning information supplied with the device.	NA	X	NA	See section 4.3.14 of the guide
Article 16 § 2.b Reconditioning of a device already on the market[2 & 3]	Article 16 § 4	NA	Limited to aspects relating to the repackaging, including any change in pack size.	NA	X	NA	See section 4.3.14 of the guide

Table 2: Applicable conformity assessment procedures and activities depending on the activity carried out by the company

Please note that certification under article 16.4 applies regardless of the class of devices already placed on the market and subject to translation, relabeling and/or repackaging.

[1] Provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State.

[2] Changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

[3] The splitting of large quantities of devices in shipping containers into smaller quantities of devices in packages or individual units for further supply is not considered a "relabeling" or "repackaging" activity within the scope of article 16 § 2, provided that the primary packaging of the device is not affected (e.g. by maintaining in particular the sterile state of a device). Consequently, this activity is not eligible for certification under article 16 § 4.
For example, the activity of a distributor who splits up syringes received in large quantities into smaller shipping containers for supply to vaccination centres and general practitioners does not fall within the scope of certification under article 16 § 4.

4.2 → Additional procedures

In addition to the conformity assessment activities described in section 4.1, one or more of the procedures described below may apply, depending on the class and type of device.

RISK CLASS AND DEVICE TYPE	ADDITIONAL PROCEDURES FOR CONFORMITY ASSESSMENT ACTIVITIES
Class III implantable devices & Class IIb active devices intended to administer/remove substances from the body	**Annex IX Section 5.1:** Clinical evaluation consultation procedure (CECP): GMED sends the clinical evaluation report to the European Commission's expert panel for an opinion. Where appropriate, the expert panel's scientific opinion is taken into account in the certification decision.
Devices incorporating a medicinal substance	**Annex IX section 5.2:** Consultation of a competent authority or the EMA: GMED sends the manufacturer's marketing authorization (MA) dossier to a competent authority designated by the European Commission or to the European Medicines Agency (EMA) to obtain an opinion on the quality and safety of the substance. The scientific opinion of the competent authority or the EMA is taken into account in the certification decision.
Devices using non-viable animal tissues/cells/ derivatives	**Annex IX section 5.3.2:** Consultation according to Regulation (EU) no. 722/2012: GMED informs the competent authorities of the member states, via its coordinating competent authority , of the results of the assessment by sending a summary of the assessment report (SER). The comments and scientific opinion of the member states are taken into account in the certification decision.
Devices composed of substances or combinations of substances that are absorbed by or dispersed locally in the human body	**Annex IX section 5.4:** Consultation of a competent authority or the EMA: for devices, or their metabolism products, which are systematically absorbed by the human body to reach their intended purpose, GMED consults a competent authority in accordance with Directive 2001/83/ EC or the EMA. The purpose of this consultation is to obtain a scientific opinion on the compliance of the device with the applicable requirements set out in Annex I of Directive 2001/83/EC. The scientific opinion of the competent authority or EMA is taken into account in the certification decision.

4.3 → Documents to be submitted as part of your formal application for certification

Your formal application for certification file must contain various documents divided into 2 different sections:
1) Documents relating to the quality management system (QMS);
2) Documents relating to the device(s).

Depending on the applicable conformity assessment procedure, you must provide the documents relating to the applicable section(s) as specified in the tables in section 4.1 of this document.

4.3.1 → Documents relating to the quality management system (QMS)

DOCUMENTS RELATING TO THE QUALITY MANAGEMENT SYSTEM (QMS)
A written declaration that no application has been lodged with any other notified body for the same device-related quality management system.
Where applicable, information about any previous application for the same device-related quality management system.
The name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system and, where applicable, the name of the authorised representative and the address of the authorised representative's registered place of business.
All relevant information on the device or group of devices covered by the quality management system.
Draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure.
Documentation relating to the quality management system set up by the manufacturer (quality manual; list of procedures, etc.).
A documented description of the procedures in place to meet the obligations arising from the quality management system and required by the regulation, as well as the manufacturer's commitment to apply these procedures*.
A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures*.
The documentation on the manufacturer's post-market surveillance system and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92.
A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures*.
A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

** The manufacturer's commitment to apply these procedures is set out in the certification contract to be signed and sent to GMED with the formal certification application..*

When requesting a QMS assessment in accordance to **Annex XI Part A § 6.1 of the MDR,** please provide the following additional documents:

The technical documentation referred to in annexes II and III of the MDR for the types approved.
A copy of the EU type-examination certificates referred to in Section 4 of Annex X; if the EU type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

4.3.2 → Documents relating to the device(s)

DOCUMENTS RELATING TO THE DEVICE(S)
A description of the design, manufacture and performance of the device
The technical documentation referred to in annexes II and III of the MDR, including : • The post-marketing clinical follow-up (PMCF) plan; • The clinical evaluation plan. ***For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the technical memo(s) with the specific additional guides developed by GMED.***

4.3.3 → Additional documents: Annex IX - Chapter I, II, and III (Quality management system + assessment of technical documentation)

As part of the conformity assessment procedure in accordance with full Annex IX (Quality management system + assessment of technical documentation), the formal application for certification must include the following documents in addition to those presented in sections 4.3.1 and 4.3.2.

DOCUMENTS RELATING TO THE DEVICE(S) Documents and information relating to this section must be submitted for each device
For implantable devices, the draft summary of safety and clinical performance (SSCP) of the device.

4.3.4 → Additional documents: Annex IX - Chapter I and III (Quality management system) with assessment of technical documentation by sampling according to section 4 of Annex IX

As part of the conformity assessment procedure in accordance with Annex IX, chapters I and III (Quality management system) with assessment of the technical documentation by sampling in accordance with section 4 of Annex IX, the formal application for certification must include the following documents in addition to those presented in sections 4.3.1 and 4.3.2 of this document.

DOCUMENTS RELATING TO THE DEVICE(S) Documents and information relating to this section must be submitted for each implantable device selected by GMED for sampling
The draft summary of safety and clinical performance (SSCP) of the device

4.3.4 → Additional documents: Annex IX - Chapter I and III (Quality management system) with assessment of technical documentation by sampling according to section 4 of Annex IX (afterpart)

ADDITIONAL AND SPECIFIC DOCUMENTS The documents and information relating to this section must be submitted for each Class IIb device intended to administer into the body and/or remove from the body a medicinal product, with the exception of the device selected by GMED for sampling
The clinical evaluation plan of the device
The clinical evaluation report of the device
The risk management file report
The label(s) applied on the device and on its packaging
The instructions for use (IFU) of the device
The post-market surveillance plan, including the Post-market Clinical Follow-up (PCMF) plan of the device

4.3.5 → Additional documents : Annex IX - Chapter I and III (Quality management system)

As part of the conformity assessment procedure according to Annex IX chapters I and III (Quality management system), the formal application for certification must include the following documents in addition to those presented in section 4.3.1 of this document.

However, the QMS assessment may be limited to certain aspects, depending on the type of device or activity carried out by your company*

*SPECIAL CASES: DOCUMENTS RELATING TO THE QUALITY MANAGEMENT SYSTEM (QMS)
For **Class I** devices **placed on the market in sterile condition**, the conformity assessment procedure is limited to aspects relating to establishing, securing and maintaining sterile conditions.
For **Class I** devices **with a measuring function**, the conformity assessment procedure is limited to aspects relating to the conformity of the devices with the metrological requirements.
For **Class I** devices **such as reusable surgical instruments**, the conformity assessment procedure is limited to aspects relating to the reuse of the device.
For **systems and procedure packs within** the meaning of **Article 22 § 3, placed on the market in sterile condition**, the conformity assessment procedure is limited to those aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged.
ADDITIONAL AND SPECIFIC DOCUMENTS Documents and information relating to this section must be submitted for each device covered by the formal application for certification
The Post-Market Clinical Follow-up (PMCF) plan of the device
The clinical evaluation plan of the device
An extract or summary of the technical documentation including the elements listed in point k of section 1.1 (Device description and specification) of Annex II of the Regulation
The instructions for use (IFU) of the device

4.3.6 → Additional documents: Annex X (Type examination) + Annex XI - Part A (Production quality assurance)

As part of the conformity assessment procedure according to Annex X (Type Examination) + Annex XI Part A (Production Quality Assurance), the formal application for certification must include the documents relating to the following devices, replacing those presented in section 4.3.2. For QMS-related documents, the formal application for certification must include the documents described in section 4.3.1.

DOCUMENTS RELATING TO THE DEVICE(S) Documents and information relating to this section must be submitted for each device covered by the formal application for certification
A written declaration stating that no application for the same type has been submitted to another notified body.
Where applicable, information regarding any previous applications for the same type
The technical documentation referred to in Annexes II and III of the Regulation, including : • The Post-Market Clinical Follow-up (PMCF) plan • The clinical evaluation plan
The draft of the summary of safety and clinical performance for class III devices and implantable devices.
Availability of a representative sample of the device (Type)
For Class III implantable devices and active class IIb devices intended to administer and/or remove a medicinal product which have been designed by modifying a device already marketed under Directive 93/42/EEC or 90/385/EEC by the same manufacturer, for the same intended purpose and for which it is explicitly demonstrated that the modifications made to the device are limited to the modifications needed in order to comply with Regulation (EU) 2017/745 and that these modifications do not adversely affect the benefit/risk ratio of the device: • A statement that the manufacturer has marketed the device in question for the same purpose, in accordance with the requirements of Directive 93/42/EEC or 90/385/EEC; • A copy of the latest issued certificate under Directive 93/42/EEC or 90/385/EEC, together with the certificate history; • A description of the modifications introduced to comply with Regulation (EU) 2017/745; • A justification demonstrating that the benefit/risk ratio is not affected.

Additional information

Within the context of this conformity assessment procedure, and according to the provisions of Regulation (EU) 2017/745, the type-examination and production quality assurance elements may be separated.

A Notified Body other than GMED may conduct the type-examination or the production quality assurance audit in order to issue an EU type-examination certificate or EU quality assurance certificate.
In that case, there will be a change in the documents to be provided together with the formal application for certification.

When a formal application for certification is filed with GMED and an EU type-examination certificate has been issued by another Notified Body for the device(s) covered by the application, the documents mentioned in the device section should not be submitted.
The application should then include those documents referred to in the quality management system section, and accompanied by:

- the technical documentation referred to in Annexes II and III of the Regulation, including the Post-Market Clinical Follow-up (PMCF) plan and the clinical evaluation plan for each device ('type') subject to the application;
- a copy of the EU type-examination certificate issued according to Regulation (EU) 2017/745 valid for each device ('type') subject to the application.

For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the technical memo(s) with the specific additional guides developed by GMED.

Where a formal application for certification filed with GMED relates solely to the type-examination, only those documents mentioned in the device section should be submitted.
Remember that in the context of this conformity assessment procedure, an EU type-examination certificate and EU quality assurance certificate are required in order to place the device(s) on the market.

Where a formal application for certification filed with GMED relates to type-examination and production quality assurance, GMED has made arrangements to issue the EU type-examination certificate and EU quality assurance certificate simultaneously, subject to acceptance of the formal application and, if and only if, the condition that the conformity assessment activities demonstrate full compliance with the relevant provisions of the Regulation.

4.3.7 → Additional documents: Annex X (Type examination) + Annex XI - Part B (Product verification)

As part of the conformity assessment procedure according to Annex X (Type Examination) + Annex XI Part B (Product Verification), the formal application for certification must include documents relating to the following devices and additional documents relating to product verification.

Class III and IIb devices, whether implantable or non-implantable and which are sold in sterile condition, can be assessed following the conformity assessment procedure described in Annex X (Type Examination) + Annex XI Part B (Product Verification) of Regulation (EU) 2017/745. In this case, it is necessary to provide the QMS documents mentioned in section 4.3.1 according to Annex XI Part A § 6.1 of the WDR.

Production quality assurance is, however, limited to aspects relating to obtaining, preserving and maintaining the sterile condition.

4.3.7 → Additional documents: Annex X (Type examination) + Annex XI - Part B (Product verification) (afterpart)

DOCUMENTS RELATING TO THE DEVICE(S) Documents and information relating to this section must be submitted for each device covered by the formal application for certification
A written declaration stating that no application for the same type has been submitted to another notified body
Where applicable, information regarding any previous applications for the same type
The technical documentation referred to in Annexes II and III of the Regulation, including: • The Post-Market Clinical Follow-up (PMCF) plan • The clinical evaluation plan
The draft of the summary of safety and clinical performance for class III devices and implantable devices
Availability of a representative sample of the device (Type)
For Class III implantable devices and active class IIb devices intended to administer and/or remove a medicinal product which have been designed by modifying a device already marketed under Directive 93/42/EEC or 90/385/EEC by the same manufacturer, for the same intended purpose and for which it is explicitly demonstrated that the modifications made to the device are limited to the modifications needed in order to comply with Regulation (EU) 2017/745 and that these modifications do not adversely affect the benefit/risk ratio of the device: • A statement that the manufacturer has marketed the device in question for the same purpose, in accordance with the requirements of Directive 93/42/EEC or 90/385/EEC; • A copy of the latest issued certificate under Directive 93/42/EEC or 90/385/EEC, together with the certificate history; • A description of the modifications introduced to comply with Regulation (EU) 2017/745; • A justification demonstrating that the benefit/risk ratio is not affected.
DOCUMENTS RELATING TO PRODUCT VERIFICATION Documents and information relating to this section must be submitted for each device covered by the formal application for certification
The draft EU declaration of conformity in accordance with Article 19 and Annex IV of the Regulation for device model undergoing the evaluation procedure
The undertaking by the manufacturer to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII of Regulation (EU) 2017/745*
The device subject of the certification application

** The commitment by the manufacturer to apply these procedures is stated in the certification contract to be signed and submitted to GMED together with the formal application for certification.*

Additional information

Within the context of this conformity assessment procedure, and according to the provisions of Regulation (EU) 2017/745, the type-examination and the product verification elements may be separated.

A Notified Body other than GMED may conduct the type-examination or product verification in order to issue an EU type-examination certificate or EU product verification certificate.
In that case, there will be a change in the documents to be provided together with the formal application for certification.

When a formal application for certification is filed with GMED and an EU type-examination certificate has been issued by another Notified Body for the device(s) covered by the application, the documents mentioned in the device section should not be submitted.
The application should then include those documents referred to in the quality management system section, and accompanied by:

- The technical documentation referred to in Annexes II and III of the Regulation, including the Post-Market Clinical Follow-up (PMCF) plan and the clinical evaluation plan, for each device ('type') subject to the application;
- A copy of the EU type-examination certificate issued according to Regulation (EU) 2017/745 valid for each device ('type') subject to the application.

For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the technical memo(s) with the specific additional guides developed by GMED.

Where a formal application for certification filed with GMED relates solely to the type-examination, only those documents mentioned in the device section should be submitted.
Remember that in the context of this conformity assessment procedure, an EU type-examination certificate and EU product verification certificate are required in order to place the device(s) on the market.

Where a formal application for certification filed with GMED relates to the type-examination and product verification, GMED has made arrangements to issue the EU type-examination certificate and the EU product verification certificate simultaneously, subject to acceptance of the formal application and, if and only if, the condition that the conformity assessment activities demonstrate full compliance with the relevant provisions of the Regulation.

4.3.8 → Additional documents: Annex XI - Part A (Production quality assurance) - Section 10 included

As part of the conformity assessment procedure according to Annex XI - Part A (Production Quality Assurance) - Section 10 inclusive, the formal application for certification must include the documents described in sections 4.3.1 and 4.3.2 of this document. However, the draft of the summary and clinical performance is only required for implantable devices.

4.3.9 → Additional documents: Annex XI - Part B (Product verification) - Section 18 included

As part of the conformity assessment procedure in accordance with Annex XI - Part B (Product Verification) - Section 18 inclusive, the formal application for certification must include the following information and documents.

Class IIa devices, implantable or non-implantable and marketed in sterile condition, may be assessed by this conformity assessment procedure in accordance with Annex XI - Part B (Product Verification) Section 18 inclusive.

In this case, the formal application for certification must include the QMS and device documentation described in sections 4.3.1 and 4.3.2 of this document. However:

1) **Production quality assurance is limited to aspects relating to obtaining, preserving and maintaining a sterile state**
2) **The draft summary of safety characteristics and clinical performance is to be provided only for implantable devices**

DOCUMENTS RELATING TO PRODUCT VERIFICATION
The draft EU Declaration of Conformity in accordance with Article 19 and Annex IV of the Regulation for the device model(s) subject to the assessment procedure
The undertaking by the manufacturer to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII of Regulation (EU) 2017/745*
The technical documentation referred to in Annexes II and III of the Regulation for each device covered by the formal application for certification
The draft of the summary of safety and clinical performance for implantable device
The device subject of the certification application

** The commitment by the manufacturer to apply these procedures is stated in the certification contract to be signed and submitted to GMED together with the formal application for certification.*

4.3.10 → Additional documents: Annex XI - Part A (Production quality assurance)

As part of the conformity assessment procedure in accordance with **Appendix XI - Part A (Production quality assurance),** the formal application for certification must include the documents relating to the QMS described in section 4.3.1.
Documents relating to the following devices are to be submitted in addition to the documents presented in section 4.3.2.

Production quality assurance may, however, be limited to certain aspects, depending on the type of device or activity carried out by your company*.

4.3.10 → Additional documents: Annex XI - Part A (Production quality assurance) (afterpart)

*SPECIAL CASES: DOCUMENTS RELATING QUALITY MANAGEMENT SYSTEM (QMS)
For **Class I** devices **placed on the market in sterile condition**, the conformity assessment procedure is limited to production for aspects relating to establishing, securing and maintaining sterile conditions
For **Class I** devices **with a measuring function**, the conformity assessment procedure is limited to production for aspects relating to the conformity of the devices with the metrological requirements
For **Class I** devices **such as reusable surgical instruments**, the conformity assessment procedure is limited to production for aspects relating to the reuse of the device
For **systems and procedure packs within** the meaning of **Article 22 § 3, placed on the market in sterile condition**, the conformity assessment procedure is limited to production for those aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged
DOCUMENTS RELATING TO DEVICE(S) **Documents and information relating to this section must be submitted for each device covered by the formal application for certification**
The Post-Market Clinical Follow-up (PMCF) plan of the device
The clinical evaluation plan of the device
An extract or summary of the technical documentation including the elements listed in point k of section 1.1 (Device description and specification) of Annex II of the Regulation
The instructions for use (IFU) of the device

4.3.11 → Additional documents: Annex IX - Chapter I (Quality management system) + Annex XIII (Custom-made devices)

As part of the conformity assessment procedure in accordance with Annex IX Chapter I (Quality management system) + Annex XIII (Custome-made devices), the formal application for certification must include the documents relating to the QMS described in section 4.3.1. Documents relating to the following devices must be submitted in addition to those presented in section 4.3.2.

DOCUMENTS RELATING TO DEVICE(S) **Documents and information relating to this section must be submitted for each device covered by the formal application for certification**
The Post-Market Clinical Follow-up (PMCF) of the device
The clinical evaluation plan of the device

4.3.12 → Additional documents: Annex XI - Part A (Production quality assurance) + Annex XIII (Custom-made devices)

As part of the conformity assessment procedure in accordance with Annex XI Part A (Production quality assurance) + Annex XIII (Custome-made devices), the formal application for certification must include the documents relating to the QMS described in section 4.3.1. Documents relating to the following devices must be submitted in addition to those presented in section 4.3.2.

DOCUMENTS RELATING TO DEVICE(S) Documents and information relating to this section must be submitted for each device covered by the formal application for certification
The Post-Market Clinical Follow-up (PMCF) of the device
The clinical evaluation plan of the device

4.3.13 → Additional documents: Article 117

As part of the conformity assessment procedure under Article 117 (assessment of the device part of a drug-device combination), the formal request for an opinion on the conformity of the device part must include the device-related documents below in addition to the device-related documents presented in section 4.3.2.

DOCUMENTS RELATING TO DEVICE(S) Documents and information relating to this section must be submitted for each device covered by the formal request for advice
The clinical evaluation plan of the device part of the drug-device combination

4.3.14 → Additional documents: Article 16 Paragraph 4 (Quality management system for activities mentioned in article 16 paragraph 2.a and/or 2.b)

As part of the conformity assessment procedure according to Article 16 Paragraph 4 (Quality management system relating to the activities mentioned in Article 16 Paragraph 2.a and/or 2.b), the formal application for certification must include the documents relating to the QMS below to replace those presented in section 4.3.1.

DOCUMENTS RELATING QUALITY MANAGEMENT SYSTEM (QMS)
A written declaration that no application for the same quality management system relating to the activities carried out under Article 16(2)(a) and/or (b) has been lodged with any other notified body.
Where applicable, information concerning any previous application for the same quality management system relating to activities carried out under Article 16(2)(a) and/or (b).
Documentation relating to the quality management system set up by the distributor or importer (quality manual; list of procedures, etc.).
A documented description of the procedures in place to comply with the obligations general incumbent on distributors or importers under the Regulation.

4.3.14 → Additional documents : Article 16 Paragraph 4 (Quality management system for activities mentioned in article 16 paragraph 2.a and/or 2.b) (afterpart)

DOCUMENTS RELATING QUALITY MANAGEMENT SYSTEM (QMS) (AFTERPART)
A documented description of the procedures in place to meet the obligations arising from the importer's or distributor's quality management system and required by article 16 paragraph 3*.
Where applicable, procedures to ensure that activities carried out under Article 16(2)(a) and/or (b) do not affect the conformity of the device with the requirements of Annex I to the Regulation.
Documentation relating to contractual relations guaranteeing compliance with certain provisions laid down in Article 16 and, where applicable, the contract(s) with any economic operator from whom the distributor or importer purchases the device.
A description of the procedures in place to ensure that the distributor or importer remains informed of any corrective action taken by the manufacturer regarding the purchased device in order to address safety issues or to bring it into compliance with the requirements of the Regulation.
A description of the procedures in place for handling non-conforming products and recalls due to activities carried out under sections a) and/or b) of paragraph 2 of article 16 of the Regulation.
A description of the procedures in place to ensure device traceability, as well as labels, instructions for use and external packaging indicating any changes made to the product(s).
A description of the procedures in place to ensure that the quality management system remains adequate and effective (internal audit, management review, etc.).

** The distributor's or importer's commitment to apply these procedures is set out in the certification contract to be signed and sent to GMED with the formal application for certification.*

4.4 → Conformity assessment reports

At the end of the conformity assessment phase, GMED draws up reports on the QMS audit and the evaluation of the device's technical documentation, which may include test reports, if applicable. These reports document the results of the assessment, including proposals/recommendations from the assessor(s) (audit, product review) for certification.
In the event of non-conformities, companies present actions to remedy them as soon as possible. GMED may also require additional audits and/or assessments to verify the implementation of corrective actions before granting certification.

V FINAL REVIEW AND CERTIFICATION DECISION-MAKING

On completion of the required conformity assessment activities, GMED carries out a final review, followed by a decision-making phase.

The final review and decision-making are carried out by personnel other than those who performed the conformity assessment activities.

The final review verifies that:
1) The assessment reports and supporting documentation, including the resolution of non-conformities identified during the assessment, are complete and sufficient in relation to the scope of the application for certification, and
2) There are no unresolved non-conformities preventing the issue of a certificate.

The decision is based on the results of the assessments, the recommendations of the assessment teams, the conclusions of the final examination and any other relevant information enabling a conclusion to be reached on compliance with the requirements of the regulations, and a decision to grant or refuse certification.

Limitations or conditions may be attached to the decision. (e.g.: request for additional information, additional audit).

If the decision-making process ends with a favorable decision, GMED generates the certificate(s) according to the applicable conformity assessment procedures, containing the information specified in appendix XII of the MDR (see table below).

Certificates are issued for a maximum validity period of five years.

CONFORMITY ASSESSMENT PROCEDURES	TYPE OF CERTIFICATES ISSUED				
	DT EU EVALUATION CERTIFICATE	EU TYPE EXAMINATION CERTIFICATE	EU PRODUCT VERIFICATION CERTIFICATE	EU QUALITY MANAGEMENT SYSTEM CERTIFICATE	EU PRODUCTION QUALITY ASSURANCE CERTIFICATES
Annex IX - Chapter I, II, and III	X			X	
Annex IX - Chapter I and III				X	
Appendix X + Appendix XI - Part A		X			X
Appendix X + Appendix XI - Part B		X	X		
Appendix XI - Part A - Section 10 included					X
Appendix XI - Part B - Section 18 included			X		
Appendix XI - Part A					X
Annex IX - Chapter I + Annex XIII				X	
Appendix XI - Part A + Appendix XIII					X
Article 16 Paragraph 4				X	

For the conformity assessment procedure under article 117, GMED issues an opinion on the conformity of the device part.

VI POST-CERTIFICATION MONITORING AND CONTROL ACTIVITIES

As of initial certification, GMED establishes and maintains a surveillance program that includes: :

1) QMS surveillance audits on the company's premises, and at its subcontractors or suppliers if GMED deems them necessary;
2) Evaluation of Periodic Safety Update Reports (PSURs) for Class III devices and implantable devices (Class III, IIb and IIa);
3) Validation of Summaries of Safety Characteristics and Clinical Performance (SSCP);
4) Assessment of technical documentation on the basis of a post-certificate sampling plan for class IIa and IIb devices (with the exception of class IIb non-WET implantable devices);
5) Evaluation of vigilance data;
6) One or more unannounced audits;
7) Assessments of substantial changes to the QMS and/or the device.

A surveillance audit is carried out at least every 12 months on the company's premises to ensure that it is maintaining the certified QMS. Surveillance activities may include physical, laboratory or other tests carried out at GMED's request. In addition, surveillance audits may be carried out at subcontractors or suppliers if required.

For Class IIa devices and certain Class IIb devices, GMED prepares the DT assessment sampling plan in accordance with the recommendations of MDCG guide 2019-13 to ensure annual DT assessments of one or more devices representative of the certified device groups.

An unannounced audit is carried out at least once every five years. This audit may take place on the premises of the manufacturer or its suppliers or subcontractors.

The manufacturer must draw up and make available to GMED periodic safety update reports (PSURs) at the frequency specified in article 86 of the MDR. PSURs for Class III devices and implantable devices must be submitted within the timeframe specified by GMED. GMED evaluates the PSUR and may take appropriate action if concerns are identified in the data.

Companies must submit any plans for substantial changes to their QMS or devices. GMED evaluates these modifications and verifies whether, after modifications, the QMS or design of a device or device type still meets the requirements of the regulation before notifying companies of its decision. Depending on the nature of the modification, GMED may perform additional conformity assessment activities such as QMS audits or TD assessments.

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