GUIDE

APPLICATION REQUEST FOR CE MARKING CERTIFICATION

REGULATION (EU) 2017/746

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GUIDE FOR GMED CUSTOMERS AND APPLICABLE ONCE GMED IS DESIGNATED UNDER REGULATION (EU) 2017/746

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GMED
LNE GROUP

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INTRODUCTION

The conditions for the submission of application for the certification of your quality management system and/or the products you wish to place on the market are defined in Regulation (EU) 2017/746.

This guide specifies the major steps of the certification process implemented by GMED according to the requirements of Regulation (EU) 2017/746.

The guide also details how to obtain a quote, and then how to submit a Formal Application for certification to GMED.

The different conformity assessment procedures applicable depending on the risk class and the specific characteristics of the device are described in sections III and IV of this guide, as well as their corresponding documents to be transmitted as part of the Formal Application request.

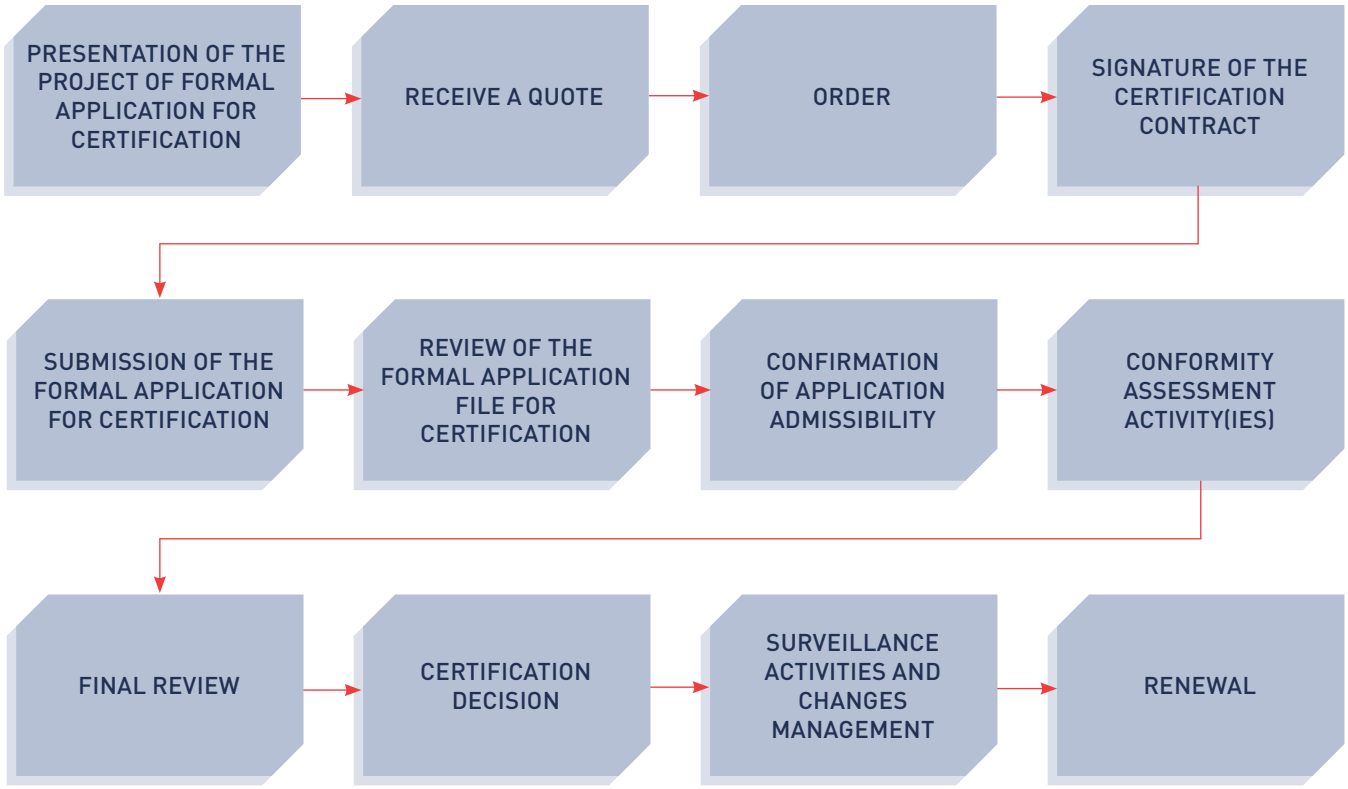
All the documents expected for a Formal Application for certification (including technical documentation) and all related correspondence must be prepared using the GMED working languages of French or English (English only for customers managed by GMED North America).
On-site audits are conducted in French or English (English only for customers managed by GMED North America).

GMED can offer its CE marking certification services within the scope of its designation (available in NANDO at http://ec.europa.eu/growth/tools-databases/nando/).

The key stages of the certification process are explained in section I.

Any requests for additional information should be e-mailed to:
- info@lne-gmed.com
- request@lne-gmed.com (customers managed by GMED North America)

CERTIFICATION PROCESS AS SET OUT IN REGULATION (EU) 2017/746



II PROCESS TO REQUEST A FORMAL APPLICATION FOR CERTIFICATION

1 → Step 1: Obtain a quote from GMED for CE marking certification

In order to present your project of formal application for certification to GMED, we invite you to complete a Single Information Form.

If you are an existing GMED client, ask your Certification Project Manager (CPM) to obtain the Single Information Form.

The form is also available for all other new clients on request by email at:

- sales@lne-gmed.com
- request@lne-gmed.com (customers managed by GMED North America)

We ask that you complete it accurately, because the information you send us will be used to:

- prepare a quote specific to your certification project;
- prepare a sampling plan, where applicable;
- decide on the admissibility of your formal application for certification, where applicable.

For existing GMED clients, please submit your completed Single Information Form to your CPM.
New clients should e-mail their information forms to:

- sales@lne-gmed.com
- request@lne-gmed.com (customers managed by GMED North America)

Having reviewed the completed form, GMED will send you a quote for a specific conformity assessment.
On receipt of your order, we will send you the certification contract accompanied by:

- the "Formal Application for certification" form;
- a list identifying the device(s) for which technical documentation must be submitted to GMED as part of submitting the Formal Application for certification;
- the "Preliminary review – IVDMD Technical Documentation" form or the "Preliminary review – Software IVDMD Technical Documentation" form.

2 → Step 2: Apply for certification with GMED

The content of the formal application for certification varies depending on the class and the specific characteristics of the device concerned, as well as the conformity assessment procedure you have chosen.

Section III summarizes (but does not supersede the text of the Regulation) the possible assessment routes available for CE marking by risk class and the specific characteristics of the device.

Section IV specifies the documents required, depending on the conformity assessment procedure you have chosen and the class and the specific characteristics of the device.

These documents form an integral part of the Formal Application file for certification.

They must be transmitted to GMED both in a duplicate and editable electronic format and paper file.

To submit a formal application for certification to GMED, you should send your designated CPM an application file containing the following:

- the completed and signed "Formal Application for certification" form;
- all the documents required for the conformity assessment procedure you have chosen and the class and the specific characteristics of the device (See the lists contained in section IV of this guide);
- the completed and signed "Preliminary review – IVDMD Technical Documentation" form or the "Preliminary review – Software IVDMD Technical Documentation" form for each technical documentation submitted as part of the formal application for certification;
- the certification contract signed by the company representative.

III THE CONFORMITY ASSESSMENT PROCEDURES APPLICABLE DEPENDING ON THE RISK CLASS AND THE SPECIFIC CHARACTERISTICS OF THE DEVICE

- **Class D device:** Annex IX Chapters I, II section 5 excluded and III
  Content of the formal application for certification:
  See this guide section 4.1

- **Class C device:** Annex IX Chapters I and III with assessment of technical documentation by sampling in accordance with section 4 (Generic group)
  Content of the formal application for certification:
  See this guide section 4.2

- **Class B device:** Annex IX Chapters I and III with assessment of technical documentation by sampling in accordance with section 4 (Category)
  Content of the formal application for certification:
  See this guide section 4.2

- **Class A sterile device:** Annex IX Chapters I and III or Annex XI
  Content of the formal application for certification:
  See this guide section 4.3

- **Class B, C and D device for self-testing and near-patient testing:** Annex IX Chapters I, II section 5.1 and III
  Content of the formal application for certification:
  See this guide section 4.4

- **Class C and D companion diagnostic device:** Annex IX Chapters I, II section 5.2 and III
  Content of the formal application for certification:
  See this guide section 4.5

IV DOCUMENTS TO BE PROVIDED IN THE FORMAL APPLICATION FOR CERTIFICATION, DEPENDING ON THE CONFORMITY ASSESSMENT PROCEDURE AND THE SPECIFIC CHARACTERISTICS OF THE DEVICE

4.1 → Annex IX Chapters I, II section 5 excluded and III

As part of the conformity assessment procedure according to **Annex IX Chapters I, II section 5 excluded and III**, the Formal Application for certification must include the following documents:

SECTION - QUALITY MANAGEMENT SYSTEM
A written declaration that no application has been lodged with any other notified body for the same device(s) related quality management system
Where applicable, information about any previous application for the same device(s)-related quality management system
The draft of one or more EU declaration(s) of conformity in accordance with Article 17 and Annex IV of the Regulation for the device model(s) covered by the conformity assessment procedure
The documentation on the manufacturer's quality management system (quality manual, list of procedures, etc.)
A documented description of the procedures in place to fulfill the obligations arising from the quality management system and those required under the Regulation, as well as the undertaking by the manufacturer to apply those procedures*
A description of the procedures in place to ensure that the quality management system remains adequate and effective, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the post-market performance follow-up (PMPF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation
A description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation, 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 performance evaluation plan(s), taking into account the state of the art

** 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.*

4.1 → Annex IX Chapters I, II section 5 excluded and III (afterpart)

SECTION - DEVICE The documents and information relating to this section must be submitted for each device covered by the formal application for certification
A description of the design, manufacture and performances of the device
The technical documentation refered to in Annexes II, III and XIII of the Regulation, including: • The post-market performance follow-up (PMPF) plan • The performance evaluation plan ***For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the corresponding technical memo « Technical documentation - Elements to be provided for assessment - Regulation (EU) 2017/746 »***
The control procedure of the finished product
The draft of the summary of safety and performance

4.2 → Annex IX Chapters I and III with assessment of technical documentation by sampling in accordance with section 4

As part of the conformity assessment procedure according to **Annex IX Chapters I and III with assessment of technical documentation by sampling in accordance with section 4**, the Formal Application for certification must include the following documents:

SECTION - QUALITY MANAGEMENT SYSTEM
A written declaration that no application has been lodged with any other notified body for the same device(s) related quality management system
Where applicable, information about any previous application for the same device(s)-related quality management system
The draft of one or more EU declaration(s) of conformity in accordance with Article 17 and Annex IV of the Regulation for the device model(s) covered by the conformity assessment procedure
The documentation on the manufacturer's quality management system (quality manual, list of procedures, etc.)
A documented description of the procedures in place to fulfill the obligations arising from the quality management system and those required under the Regulation, as well as the undertaking by the manufacturer to apply those procedures*
A description of the procedures in place to ensure that the quality management system remains adequate and effective, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the post-market performance follow-up (PMPF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation
A description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation, 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 performance evaluation plan(s), taking into account the state of the art

** 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.*

SECTION - DEVICE The documents and information relating to this section must be submitted for each device selected by GMED in the context of sampling plan
A description of the design, manufacture and performances of the device
The technical documentation refered to in Annexes II, III and XIII of the Regulation, including: • The post-market performance follow-up (PMPF) plan • The performance evaluation plan ***For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the corresponding technical memo « Technical documentation - Elements to be provided for assessment - Regulation (EU) 2017/746 »***
The draft of the summary of safety and performance for class C devices

4.3 → Annex IX Chapters I and III or Annex XI

As part of the conformity assessment procedure according to **Annex IX Chapters I and III or Annex XI**, the Formal Application for certification must include the following documents:

SECTION - QUALITY MANAGEMENT SYSTEM
A written declaration that no application has been lodged with any other notified body for the same device(s) related quality management system
Where applicable, information about any previous application for the same device(s)-related quality management system
The draft of one or more EU declaration(s) of conformity in accordance with Article 17 and Annex IV of the Regulation for the device model(s) covered by the conformity assessment procedure
The documentation on the manufacturer's quality management system (quality manual, list of procedures, etc.) in connection with aspects related to obtaining, preserving and maintaining the sterile condition of the device
A documented description of the procedures in place to fulfill the obligations arising from the quality management system and those required under the Regulation, in connection with aspects related to obtaining, preserving and maintaining the sterile condition of the device, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the post-market performance follow-up (PMPF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation
A description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the performance evaluation plan(s) and a description of the procedures in place to keep up to date the performance evaluation plan(s), taking into account the state of the art

** 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.*

4.4 → Annex IX Chapters I, II section 5.1 and III

As part of the conformity assessment procedure according to **Annex IX Chapters I, II section 5.1 and III**, the Formal Application for certification must include the following documents:

SECTION - QUALITY MANAGEMENT SYSTEM
A written declaration that no application has been lodged with any other notified body for the same device(s) related quality management system
Where applicable, information about any previous application for the same device(s)-related quality management system
The draft of one or more EU declaration(s) of conformity in accordance with Article 17 and Annex IV of the Regulation for the device model(s) covered by the conformity assessment procedure
The documentation on the manufacturer's quality management system (quality manual, list of procedures, etc.)
A documented description of the procedures in place to fulfill the obligations arising from the quality management system and those required under the Regulation, as well as the undertaking by the manufacturer to apply those procedures*
A description of the procedures in place to ensure that the quality management system remains adequate and effective, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the post-market performance follow-up (PMPF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation
A description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation, 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 performance evaluation plan(s), taking into account the state of the art

** 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.*

4.4 → Annex IX Chapters I, II section 5.1 and III (afterpart)

SECTION - DEVICE The documents and information relating to this section must be submitted for each device covered by the formal application for certification
A description of the design, manufacture and performances of the device
The technical documentation refered to in Annexes II, III and XIII of the Regulation, including: • The post-market performance follow-up (PMPF) plan • The performance evaluation plan ***For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the corresponding technical memo « Technical documentation - Elements to be provided for assessment - Regulation (EU) 2017/746 »***
The control procedure of the finished product, for class D devices
The draft of the summary of safety and performance for class D and C devices
The test reports, including results of studies carried out with intended users
An example of the device
The data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing
The information to be provided with the device on its label and its instructions for use

4.5 → Annex IX Chapters I, II section 5.2 and III

As part of the conformity assessment procedure according to **Annex IX Chapters I, II section 5.2 and III**, the Formal Application for certification must include the following documents:

SECTION - QUALITY MANAGEMENT SYSTEM
A written declaration that no application has been lodged with any other notified body for the same device(s) related quality management system
Where applicable, information about any previous application for the same device(s)-related quality management system
The draft of one or more EU declaration(s) of conformity in accordance with Article 17 and Annex IV of the Regulation for the device model(s) covered by the conformity assessment procedure
The documentation on the manufacturer's quality management system (quality manual, list of procedures, etc.)
A documented description of the procedures in place to fulfill the obligations arising from the quality management system and those required under the Regulation, as well as the undertaking by the manufacturer to apply those procedures*
A description of the procedures in place to ensure that the quality management system remains adequate and effective, as well as the undertaking by the manufacturer to apply those procedures*
The documentation on the manufacturer's post-market surveillance system and, where applicable, on the post-market performance follow-up (PMPF) plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation
A description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87 of the Regulation, 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 performance evaluation plan(s), taking into account the state of the art

** 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.*

4.5 → Annex IX Chapters I, II section 5.2 and III (afterpart)

SECTION - DEVICE The documents and information relating to this section must be submitted for each device covered by the formal application for certification
A description of the design, manufacture and performances of the device
The technical documentation refered to in Annexes II, III and XIII of the Regulation, including: • The post-market performance follow-up (PMPF) plan • The performance evaluation plan ***For recommendations regarding the form and content of the technical documentation to be submitted to GMED, please consult the corresponding technical memo « Technical documentation - Elements to be provided for assessment - Regulation (EU) 2017/746 »***
The control procedure of the finished product, for class D devices
The documentation enabling the characteristics and performance of the device to be understood, and enabling conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned
The draft of the summary of safety and performance

V TYPES OF SERVICES COVERED UNDER REGULATION (EU) 2017/746

TYPES OF SERVICES PROVIDED	CORRESPONDING ANNEXES OF REGULATION (EU) 2017/746
On-site-audit	Annex IX Chapters 1 and 3 Annex XI
Systematic assessment of technical documentation	Annex IX Chapter 2
Testing	Annex IX Chapters 1 and 3 Annex IX Chapter 2
Use of external expertise	Annex IX Chapters 1 and 3 Annex IX Chapter 2
Special procedures	Annex IX Chapter 2 section 5.1 (Class D, C and B self-testing and near-patient testing device) Annex IX Chapter 2 section 5.2 (Companion diagnostic)
EUDAMED relatives procedures	Article 26 Article 29 Article 81
UE reference laboratory	Annex IX Chapter 2
Expert panels	Annex IX Chapter 2

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