GMED LNE GROUP Newsletter

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Version Française

COMBINED AUDITS MDD/AIMDD AND MDR: REQUIREMENTS AND IMPACT ON THE QUALITY MANAGEMENT SYSTEM

The date after which "legacy devices"[1] can no longer be placed on the market or put into service pursuant Medical Device Directive 93/42/EEC (MDD) and the Active Implantable Medical Device Directive 90/385/EEC (AIMDD) has been extended following the publication of Regulation (UE) 2023/607.

Hence, a lot of manufacturers will have coexisting in their product portfolio "legacy devices" and devices certified under the Medical Device Regulation (UE) 2017/745 (MDR) for a longer period.

Combined audit can then become an exercise to discriminate the requirements between devices covered by MDD/AIMDD and devices undergoing an MDR conformity assessment procedure, or devices already certified under the regulation.

This newsletter is intended to explain the requirements of combined audit and its impact on the quality management system (QMS).

A ARTICLE 120 AND APPLICABLE MDR REQUIREMENTS FOR "LEGACY DEVICES"

Article 120 "Transitional provisions" of the MDR describes in section 3 the requirements that must be fulfilled since its date of application (DoA) for legacy devices. These requirements relate to post-market surveillance (articles 83 to 86), market surveillance (Article 93), vigilance (articles 87 to 90), and registration of economic operators and of devices (articles 29 and 31). Manufacturers must have made adjustments in their QMS to conform to these requirements.

For more details, a table lists the applicable MDR requirements for "legacy devices" in the guidance MDCG 2021-25. In addition, the following verification should be made prior and during surveillance audits:

- Presence of a transition plan for the MDR compliance;
- Provisions to identify and notify substantial and significant changes to the notified body (NB). Any identification during the audit of a modification that should have been notified to the NB, will result in the opening of a non-conformity form;
- Determine the scope of devices covered by MDD/AIMDD

Terminology from guide MDCG 2021-25:

[1]"Legacy devices" should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e., 26 May, 2021) if certain conditions are fulfilled. Those devices can be:

- *Devices which are Class I under the MDD/AIMDD, for which an EC declaration of conformity was drawn up prior to 26 May, 2021, and for which the conformity assessment procedure under the MDR requires the involvement of a NB;*
- *Devices covered by a valid EC certificate issued in accordance with the AIMDD or the MDD prior to 26 May, 2021.*

certificates: which devices are/will be subject to a conformity assessment procedure under MDR and which devices will cease to be marketed after 26 May, 2024. Any change should be communicated to the audit team.

B REQUIREMENTS RELATED TO POSSIBLE SCENARIOS

Depending on the specific situation of a manufacturer, audits are to be performed under Article 120(3) MDR, and/or according to Article 52 of the MDR and the respective procedures set out in Annexes IX chapter I and III or XI part A.

The different scenarios listed below can be met and will result in an audit respectively to the situation of the manufacturer:

- Manufacturers of "legacy devices" that have not lodged a formal application under MDR or devices that are subjects of a formal application but for which a Conformity Assessment Procedure hasn't started yet:
  - Surveillance audit is performed according to the requirements of MDD/AIMDD and the NB verifies the implementation of provisions set up in Article 120(3).

- Manufacturers of "legacy devices" whose MDR conformity assessment procedure is ongoing:
  - Surveillance audits may be performed according to the MDR.

- Manufacturers of "legacy devices" and devices certified under MDR for the same and/or partially different types of devices:
  - MDR audits and surveillance audits may be performed according to the MDR.

In any case, an assessment of the individual circumstances will be performed.

It is important to note that no later than 26 September, 2024, the surveillance of the legacy devices can only be performed by the NB who received the formal application for certification and concluded the written agreement with the manufacturer.

C REQUIREMENTS RELATED TO THE QMS

The QMS of manufacturers of devices certified under MDR[2] must comply with the requirements of Article 10(9) of the MDR. Those requirements align with the requirements of EN ISO 13485:2016 and EN ISO 13485/A11:2021, with some supplements:

- The need for a regulatory compliance strategy;
- Identification of applicable general safety and performance requirements, and methods to address them;
- Risk management as set out in section 3 of Annex I of the MDR;
- Clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;
- Verification of the UDI assignments made in accordance with Article 27(3);
- A post-market surveillance system set up, implemented, and maintained in accordance with Article 83.

Those requirements become applicable to manufacturers of "legacy devices" from May 26, 2024, at the latest.
Until this date, the QMS of "legacy devices" manufacturers must comply with:

- Particular requirements of MDD/AIMDD;
- Requirements listed in Article 120(3) and following of the MDR.

[2] *MDR devices are those that are placed on the market as being in conformity with the MDR other than "legacy devices".*

Conclusion

Generally speaking, the MDR conforms with, supplements, or strengthens the MDD/AIMDD requirements. Thus, despite the coexistence of MDD/AIMD-compliant and MDR-compliant devices on the market, until December 31, 2028, at the latest, MDD/AIMD requirements are gradually being replaced by MDR requirements.

Finally, with Regulation (EU) 2023/607 amending Regulation (EU) 2017/745, as of May 26th, 2024, all manufacturers holding MDD/AIMDD certificates covering "legacy devices" included in a formal application, will be required to have implemented a QMS in accordance with Article 10(9) of the regulation.

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N°13 | NOVEMBER 2023

To go further

TRAININGS FOR AMERICA REGION

European Medical Devices Regulation (EU) 2017/745
2-day training session | Jan. 30-31, 2024 | Virtual classroom

→ CHECK OUT THE PROGRAM

The Clinical Evaluation Report (CER) requirements under the EU MDR 2017/745
2 half-days training session | April 9-10, 2024 | Virtual classroom

→ CHECK OUT THE PROGRAM

Post Market Surveillance and Vigilance
1-day training session | March 19, 2024 | Virtual classroom

→ CHECK OUT THE PROGRAM

TRAININGS FOR OTHER REGIONS

Apply the requirements of the European Medical Device Regulation (EU) 2017/745
SA56 | 2-day training session | Virtual classroom

Adapt your quality management system to ISO 13485 v2016
SA19 | 2-day training session | Virtual classroom

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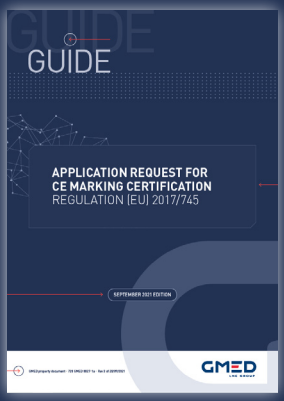
GMED GUIDE

Application request for CE marking certification – Regulation (EU) 2017/745



This guide specifies the main steps of the certification process implemented by GMED according to the requirements of Regulation (EU) 2017/745 and also details how to obtain a quote and submit a Formal Application for certification with GMED.

You will also find in this guide the different conformity assessment procedures applicable depending on the risk class, the type of device as well as their corresponding documents to be transmitted as part of your Formal Application request.

→ LEARN MORE

GUIDANCES AND REGULATIONS

- **Regulation (EU) 2023/607**
- **Guide MDCG 2021-25**: Regulation (EU) 2017/745, application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC and 93/42/EEC
- **Guidance MDCG 2022-4**: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD
- **Position Paper MDCG 2022-14**: Transition to the MDR and IVDR, notified body capacity and availability of medical devices and IVDS

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