Medical Devices

Regulatory Newsletter 05/2023

Dear customer,

In our newsletter for medical device testing, certification and international approval, we will provide you with current information and updates on regulatory requirements. In this issue you can find detailed information about the extension of the transition period for MDR. In the second part we answer frequently asked questions about the MDR transition.

We hope you enjoy reading and that you find helpful information for your everyday work!

Your TÜV Rheinland Products Team

MDR and IVDR transition extended

LATEST AMENDMENT OF THE MEDICAL DEVICES REGULATION EU 2017/745 ALLOWS TO APPLY FOR AN EXTENSION OF THE TRANSITION PERIOD

With it's publication in the European Journal on the 21st of March 2023, the European Regulation (EU) 2023/607 amending the European Regulations on Medical Devices (EU) 2017/745 (MDR) and (EU) 2017/746 on in-vitro Diagnostics (IVDR) has entered into force. The most important aspect of the new regulation is the extension of the transition periods from the Medical Device Directive MDD to the Regulation until December 2027 for high-risk medical devices and to December 2028 for all other medical devices (note that the transition period for IVD has already been extended in January 2022).

The publication of the amendment became necessary after the European Commission realized that the initial deadline for transition until May 2024 would not be feasible for a number of medical device manufacturers, leading to the threat of a critical shortage of urgently needed medical devices and their accessories within the European Union. Not only are the requirements for manufacturers for product certification according to MDR more demanding than they were under MDD, but also the designation of Notified Bodies (NB) according to the new regulation has proven to be extremely time-consuming, leading to the situation that only half as many NBs are able to certify according to MDR than was the case for MDD. TÜV Rheinland LGA Products GmbH was among the one of the first three NBs to apply and receive their designation for CE-certification under to the new regulation and is doing its best to help its customers to make the transition.

The extension of the transition period now provides some relief to medical device manufacturers and their Notified Bodies to adapt to MDR, but it remains a challenge. Although the new regulation defines the requirements that need to be met (the CE certificate covering the products to be transitioned was valid from the 24th of May 2021, the manufacturer's quality management system must comply with the MDR requirements by May 2024, the manufacturer needs to submit a formal application for all devices that are to be transitioned within the extended time frames by the 24 of May 2024 and a detailed contract between Notified Bodies and their customers covering the transition details need to be in place) a lot of details are still to be determined. Guidance on the new regulation is currently being developed by various working groups at European Level (MDCG, Team NB, MedTech Europe), and TÜV Rheinland is closely monitoring the developments. At the moment, there are still some open questions that cannot be answered, such as the issuance and the possible format of a "confirmation letter" upon receipt of the application to be submitted by May 25th, 2024, but we will make sure to keep you informed as details and guidelines on these topics will become available in the coming weeks. Please expect more information within the next news letters to follow. As a service, please also refer to the questions and answers attached here below.

The MDR transition in Questions and Answers

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Head of Certification Medical
TÜV Rheinland LGA Products GmbH

1. IS A NEW APPLICATION AND CONTRACT ON TRANSITION TIMELINE NECESSARY FOR EXISTING APPLICATIONS UNDER MDR WHICH HAVE BEEN MADE BEFORE MAY 2024?

Not from a formal standpoint, as application and contract on submission would already be available for those devices. However, it may be preferable to add the devices in transition to the overall application as the "letter of confirmation" that will be sent back by the NBs listing all products that fall under the extension may have a "certificate-like" character to serve as evidence that the listed articles may still be placed on the market even though the initial certificate has expired.

2. IF EXISTING CERTIFICATION UNDER MDD END IN 2023, WILL THERE BE AN AUTOMATIC EXTENSION TILL MAY 2024?

The requirements that allow medical device manufacturers to benefit from the extended transition times as published in regulation 607/2023 are that the MDD certificate was not only valid in May 2021 but also to the point of time of the publication of the amending regulation in the European Journal the 20th of March 2023. Certificates with an expiry date later than March 2023 will remain valid "by law". Details on supporting actions to be taken by legal manufacturers and Notified Bodies are currently being elaborated and finalized.

3. FOR PRODUCTS WHICH ARE TRANSFERRED TO MDR ACCORDING TO THE TRANSITION PLAN UNTIL 2026/2027, WHICH EVIDENCE WILL BE REVIEWED DURING AUDITS (E.G. MARKET SURVEILLANCE, POST MARKET CLINICAL FOLLOW-UP)?

All requirements that were added to the Quality Management System to comply with MDR as they apply to MDR certified medical devices (data collected within post-market surveillance such as evaluation of that data, SS(C)Ps and PSURs (as they apply), updates to clinical evaluations, ongoing PMCF…)

4. FOR A LEGAL MANUFACTURER IN THE LATE DEVELOPMENT PHASE OF A STATE-OF-THE-ART MEDICAL DEVICES WHICH IS INTENDED TO SUBSTITUTE OLDER VERSIONS OF DEVICES: WOULD THE MANUFACTURER BE ABLE TO:

a) File an application for the new state-of the art devices explaining that when CE marked, they will replace/substitute the "legacy" devices prior to the 26th of May 2024?

Yes, that is possible.

b) Would a legal manufacturer then be able to sell the "legacy" devices after 26 May 2024, until approval has been given for the new devices (e.g., sell MDD devices that will not be transferred to MDR but will be substituted by state-of-the-art version of the legacy devices)?

Yes.

c) In the application, is there a need for clarifying or rationalizing why the new devices are seen as substitute for legacy devices? i.e., showing similarities between legacy and new devices, for instance:

- Intended purpose & clinical claims
- Article mapping old-new
- Technical aspects
- Production aspects

Yes, proof of the substitute device replacing the MDD-certified legacy device should be made as to benefit from the extension of the transition periods for the legacy device until it is replaced by the new device; Main aspect: intended use.

5. WHAT IS THE CONTENT OF THE AGREEMENT WHICH WILL BE SIGNED BETWEEN THE MANUFACTURER AND NOTIFIED BODY?

The potential content for the agreement such as a template are still to be defined/drafted; it was suggested that the agreement defines the road map as to when legal manufacturers will file their individual MDR-applications as to enable planning of resources for both sides.

6. IN CASE OF SIGNED AGREEMENT BY 2024, WHEN DOES THE TECHNICAL DOCUMENTATION NEED TO BE COMPLETED? AT THE DATE OF THE SIGNED AGREEMENT OR WHEN SUBMISSION OF THE TECHNICAL DOCUMENTATION IS ACTUALLY MADE.

With individual submission.

You Need Further Support?

Find more information about medical device testing and certification services on our website. Our experts are available at any time to answer your specific questions or create a customized, non-binding offer. Please use our contact form to submit your request so we can guide you quickly to the right expert in your region.

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