



Questions and Answers on the new European Medical Devices Regulation (MDR 2017/745)

Our experts have compiled and answered the most frequently asked questions for you. Would you like to find out more about the new MDR 2017/745? Our experts will be pleased to inform you personally. **Contact us today!**

GENERAL REMARKS

The revised European Medical Device Regulation is considerably more comprehensive and more detailed than its predecessor. Guidelines have been provided due to the complexity of the newly created regulatory framework. In addition, the legal framework of the regulation includes amendments to so-called delegated acts and implementing acts, which must be drafted, agreed upon and published accordingly.

1. WHAT IS THE EUROPEAN MEDICAL DEVICE REGULATION (MDR)?

In order to meet the constantly evolving requirements for medical devices, institutions of the European Union such as the Commission, the Parliament and the Council held lengthy negotiations and have agreed to a compromise on a complete overhaul of the legal regulations for medical devices.

The new text was published as [regulation](#) – and as such as directly applicable law – on May 5, 2017. The new [MDR \(Medical Device Regulation\) 2017/745](#) is set to replace the existing national requirements of the Medical Device Directive (MDD 93/42/EEC) within a specified time frame.

Further information on the revision of the Medical Device Regulation can also be found on the [EU website](#).

2. WHAT IS THE CENTRAL DATABASE – EUDAMED AND UDI?

A key element of the MDR is the introduction of a European database in order to increase transparency, ensure traceability of [medical devices](#), and to facilitate the flow of information between manufacturers and users of medical devices, Notified Bodies, EU member states and the European Commission. Eudamed will integrate various information or databases, e.g. for the registration of products with a unique UDI (Unique Device Identification) number as well as for market players, conformity assessment procedures, certificates, Notified Bodies or even incidents and clinical trials.

3. WHAT WILL CHANGE FOR THE NOTIFIED BODIES?

Now, the notification procedures and the procedures for monitoring Notified Bodies are regulated in more detail, they are stricter and meant to result in the further harmonization of the requirements. This (enables Notified Bodies to comply with current requirements and thus) ensure(s) an even higher level of quality and safety for medical devices. Furthermore, the Notified Bodies are required, among other things, to employ more physicians or clinical experts and to ensure a rotation of lead auditors for surveillance audits.

4. WHAT ARE UNANNOUNCED AUDITS?

Notified Bodies are under obligation to conduct an unannounced audit at least once every five years. These audits increase the probability that manufacturers are manufacturing their products in full compliance with the applicable regulations. The inspection of products is an important element of these audits.

5. WHAT ARE THE NEW CHALLENGES FOR MANUFACTURERS, SUPPLIERS, IMPORTERS, DISTRIBUTORS AND AUTHORIZED REPRESENTATIVE IN EUROPE?

For a long time, there have been extensive requirements that manufacturers in the EU had to meet. These requirements are now specified in more detail and extend across the entire medical device supply chain. Systems for risk management, vigilance and post-market surveillance must be implemented and interlinked as integral parts of the overall [quality management](#). The resulting information must be systematically analyzed by the manufacturer and documented in periodic reports to continuously update the technical documentation and support a reliable risk assessment. Individuals entrusted with conducting clinical evaluations must demonstrate a high level of technical expertise. In addition, manufacturers must employ a specific person who is responsible for monitoring compliance with regulatory requirements. Furthermore, manufacturers are required to maintain liability insurance for the financial coverage of any damage that may be caused by defective products.

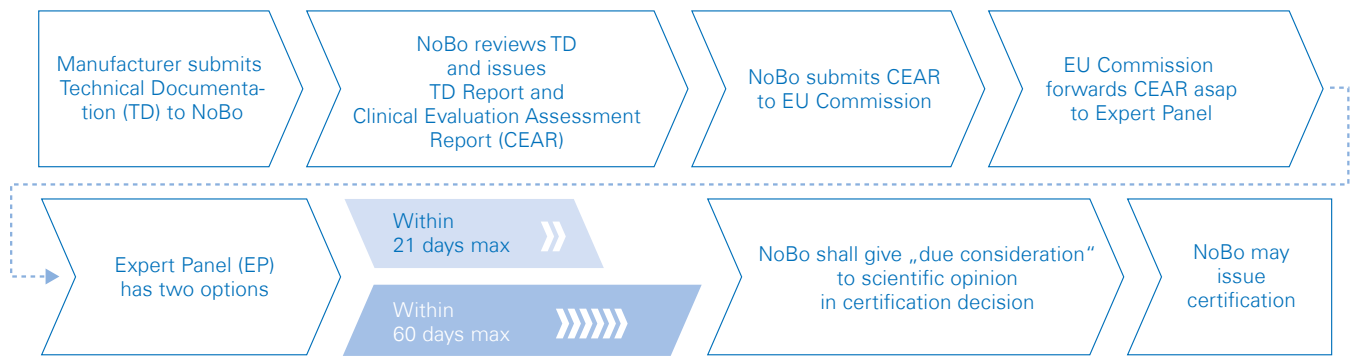
6. WHAT IS THE DUAL SAFETY MECHANISM FOR HIGH-RISK PRODUCTS?

The basic principle for carrying out conformity assessment procedures remains the same. However, under the MDR, the following products are now subject to a **dual safety mechanism**:

- Implantable Class III products
- Active Class IIb products intended to administer and/or remove medicinal products, body liquids or other substances to or from the body to which common specifications do not apply or if this is the first certification for such a product.

The **dual safety mechanism** consists of:

1. Pre-market clinical consultation procedure
2. Post-market control of the conformity assessments (scrutiny procedure)



7. WHAT PRODUCTS WITH A SOLELY AESTHETIC OR NON-MEDICAL INTENDED USE AS SPECIFIED BY THE MANUFACTURER ARE NOW COVERED BY THE MDR?

Such products in general fall outside the scope of the Medical Device Regulation. However, aesthetic products or products for non-medical use that are similar in function and risk profile to products intended for medical use are covered by the new regulation. A list of these products can be found in Annex XVI of the MDR. These products include e.g. colored contact lenses or medical devices for liposuction.

8. WHAT ARE THE NEW REGULATIONS FOR THE REUSE OF MEDICAL DEVICES?

Member states may either permit or prohibit the reuse or recycling of single-use products at the national level. Under the new MDR, such a “recycler” is considered a manufacturer and must therefore comply with both the regulation requirements and applicable national mandates. The EU Commission has yet to define common specifications on this topic.

In the future, manufacturers of Class I reusable surgical instruments will also need to involve a Notified Body. This Notified Body however will only review the aspects related to the reuse of the products.

9. WHAT IS THE NEW CLASSIFICATION RULE IN THE MDR THAT APPLIES ONLY TO SOFTWARE?

Under the new Rule 10a, software designed to provide data used to make decisions for diagnostic or therapeutic purposes is now classified as Class IIa. This also applies to software that previously fell under Class I.

However, if those decisions have implications that may directly or indirectly cause death or lead to an irreversible deterioration of health, the software is now classified as Class III.

This is new for software that is neither part of a Class III medical device nor controls or influences such a device.

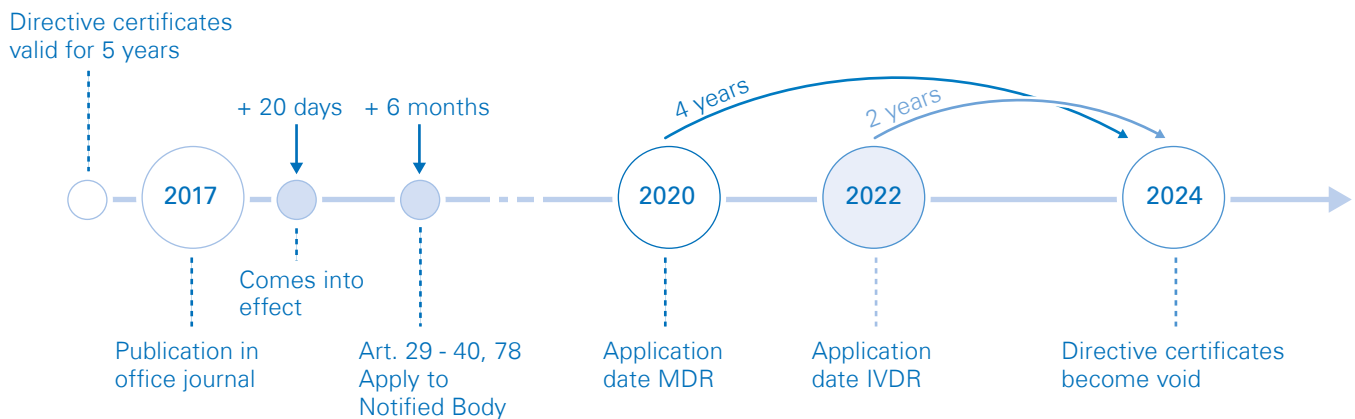
10. WHEN DO MEDICAL DEVICE MANUFACTURERS NEED TO COMPLY WITH THE REQUIREMENTS OF THE NEW MDR?

Starting May 26, 2020, manufacturers and new products must meet the new MDR requirements in order to be marketed in the European Union.

Medical devices that are still covered by a Directive certification may continue to be marketed until the end of the validity of the certificate, but no later than May 26, 2024. However, this transitional period only applies if the requirements continue to be monitored by the previous Notified Body, if the modified requirements are being met, such as the surveillance of the products placed on the market or the reporting of adverse events; and if no significant changes are made to the design or the intended purpose of these products.

11. WHAT HAPPENS IF MY CERTIFICATE IS NOT ISSUED BEFORE THE END OF THE TRANSITION PERIOD?

There is a transition period for manufacturers to apply for the new MDR certification for devices currently certified under the Medical Device Directive (MDD) or the **Active Implantable Medical Device Directive (AIMDD)**.



Certificates issued during the transition period under the MDD and AIMDD remain valid for the entire period, unless they exceed four years after the date of application. The validity of MDD and AIMDD certificates after the date of application depends on the compliance with provisions specified in Article 120 (3).

If you do not receive a certification during the transition period and your MDD certificate expires during that time, you must withdraw your products from the EU market until they are certified under the new MDR.

12. WHICH PRODUCTS ARE COVERED BY THE MDR?

The Medical Device Regulation covers all medical devices that previously fell in the scope of the Medical Device Directive (MDD, 93/42/EEC) and all products regulated under the previous Active Implantable Medical Device Directive (AIMDD, 90/385/EEC).

13. WILL THERE BE ANY CHANGES TO THE CLASSIFICATION OF MY MEDICAL DEVICE?

The previous system with four classes remains in place. Classification for most products will not change, but there is some revision where the material properties of otherwise unmodified products may lead to classification changes – for example nanomaterials. A number of software products may also be subjected to changes in classification (see question 9).

Furthermore, in a new class of Class I medical devices, manufacturers of reusable surgical instruments are now required to involve a Notified Body for MDR to assist with conformity assessment.

Classification rules can be found in Annex VIII of the new regulation.

Another new provision allows for MDR regulation of some products without medical purpose. The preliminary list of those products can be found in Annex XVI.

14. MAY I MAKE ANY CHANGES AFTER MAY 26, 2020 TO THE INTENDED USE OF PRODUCTS THAT I WOULD LIKE TO CONTINUE TO MARKET AS MDD-CERTIFIED PRODUCTS?

The MDR specifies that no changes may be made to the intended use or the design of medical devices to be placed on the market as MDD-certified products during the transition period. Any planned changes that had to be previously registered under the MDD must still be reported to the Notified Body.

Products that are to undergo changes to their intended use or design must first pass a conformity assessment procedure under the MDR.

15. WHAT WILL CHANGE FOR MEDICAL DEVICES THAT INCLUDE MEDICINAL PRODUCTS?

The technical requirements for these products remain unchanged. As part of the conformity assessment the MDR stipulates that such Class III products continue to be subject to a consultation procedure with a medicinal products competent authority in order to assess the quality and safety of the drug component and to evaluate the benefit/risk balance of the ingredient in the product.

16. WHAT WILL CHANGE FOR MY MEDICAL DEVICES THAT ARE MADE USING MATERIALS OF ANIMAL ORIGIN?

The technical requirements for these products remain unchanged. Under the MDR, these Class III products continue to be assessed taking into account the additional requirements of Regulation (EU) No 722/2012.

17. HOW CAN MANUFACTURERS PREPARE FOR THE NEW MDR?

In order to successfully transition from the Directives to the requirements of the new Regulation, manufacturers must be aware of the necessary adjustments to be made to their quality management system and have prepared a detailed implementation plan. The necessary audits should be appropriately scheduled. Planning certification towards the end of the transition period carries high risk, because, after May 2024, manufacturers will be prohibited from placing products without valid MDR certification on the market. An effective strategy should be discussed with the future Notified Body and realistic plans should be in place to allow for the time required to transition and to evaluate the technical documentation according to the MDR requirements.

18. CAN I ESTIMATE THE COSTS FOR MDR CERTIFICATION BASED ON THE COSTS FOR MDD CERTIFICATION?

The cost expenditure of the Notified Bodies for the MDR notification has increased significantly compared to notifications under the Directives. Efforts to maintain the new

MDR notification have increased as have the specified tasks requiring Notified Bodies to monitor certified manufacturers throughout the validity period of the MDR certificate(s), resulting in higher costs.

Manufacturers internal expenses are also increasing, not least because many manufacturers cannot directly switch completely from the MDD to the MDR, and must therefore have both systems certified in parallel for a certain period of time.

Costs for the new conformity assessments will therefore significantly rise in comparison over the period of five years.

19. WHEN WILL TÜV RHEINLAND START PROVIDING MDR SERVICES?

We are recognized as the fifth Notified Body for the Medical Devices Regulation MDR 2017/745. Following the publication in the Commission's NANDO database, we will be accepting applications for MDR conformity assessments.

For a certification procedure, the costs are calculated individually on an hourly basis, taking into account the size of the company, the number of locations, and the complexity of the products.

Our hourly rates* for the activities of TÜV Rheinland LGA Products GmbH (Germany) are as follows:

Audit activities according to the MDR	250 Euro
Conducting unannounced audits under the MDR	250 Euro
Processing notifications of change or significant changes	250 Euro
Review of technical documentation according to the MDR	350 Euro
Involvement of a clinical expert in the review of the technical documentation	350 Euro

*Hourly rates may vary by region

WE ARE HAPPY TO PERSONALLY INFORM YOU ABOUT THE NEW MDR 2017/745 MEDICAL DEVICE REGULATION. MAKE AN APPOINTMENT WITH OUR EXPERTS!

[ONLINE CONTACT](#)

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