

Important information for health care professionals, such as hospitals, homes, health care providers, surgeons and other users and operators of medical

Berlin, July 2020

Status and implementation of the new European Regulation 2017/745 on Medical Devices (MDR)

You as a health care provider will be directly affected by the impact of the new Medical Device Regulation. Therefore we would like to inform you about the application and the status of the MDR:

The date of application of the European Medical Device Regulation (EU) 2017/745 (MDR) is drawing closer, even if the date of application was postponed by one year because of the COVID-19 pandemic. From May 26th 2021, the new law must be applied in the EU internal market and replaces the previous European directives (Medical Device Directive - MDD, Active Implantable Medical Device Directive - AIMDD), which were implemented in Germany via the Medical Devices Act (MPG) and the associated regulations.

Please note that this change does not affect any products you already use or that are already in your stock.

The MDR will introduce a completely revised regulatory system that will replace the current market access system for medical devices - from implants to reusable surgical instruments or software.

This requires not only a new certification of hundreds of thousands of existing higher class medical devices, but also a new designation of the so-called Notified Bodies (certification bodies for medical devices) throughout the EU. The process of recertification usually takes at least 6 months for each product. At the same time, the quality management system of the respective manufacturer must be certified.

Devices for which a Notified Body had to be involved in the conformity assessment under the previous legal framework (MDD/AIMDD) can benefit from a transitional period until May 2024 at the latest. Additionally these products can continue to be provided with the existing directive certificates until May 27th 2025 and can be used by you as a health care provider. One of the conditions for this transitional period is that the directive certificates remain valid (maximum of the validity is 5 years). At present, all manufacturers are seeking to ensure the uninterrupted supply of medical devices beyond May 26th 2021.

Since the MDR corrigendum of December 27th 2019, also Class I products that require a Notified Body for certification under the MDR benefit from this transitional period. For example reusable surgical instruments as well as higher-classified devices like medical software, medical devices containing nanomaterial and substance based medical devices (according to Art. 120 (3) subparagraph 1 MDR).

This transitional period does not apply to Class I products for which no Notified Body is involved in the

conformity assessment according to the MDR. These must fully comply with the MDR on May 26th 2021.

The biggest challenge for the new certification of existing products of higher classes is the fact that out of 55 existing Notified Bodies in Europe, only 14 (as of July 2020) are currently notified under the new regulation and are therefore allowed to certify medical devices according to the MDR. This creates an enormous bottleneck in the MDR certification of products, but also in the quality management certification of manufacturers.

In total, the Notified Bodies have to assess more than 500,000 medical devices according to the rules of the MDR and, in case of success, have to reissue more than 50,000 product certificates and more than 10,000 quality management certificates. In view of this workload and the limited number of Notified Bodies, delays cannot be ruled out.

The industry is meeting this challenge by making use of the transition period until May 26th 2025 and working closely with Notified Bodies to ensure a smooth and uninterrupted transition to the new Regulation. At the same time, all industrial companies are working on the implementation of the MDR with a high input of resources and a clear focus.

Please note:

- > **Medical devices purchased before May 26th 2021, and**
- > **Medical devices purchased between May 26th 2021 and May 26th 2025,**
may be distributed and used during this period under both the old law (MDD/AIMDD/MPG) and the new law (MDR).
- > **Medical devices purchased after May 26th 2025,**
may only be distributed and used under the new legal framework (MDR). You can use these medical devices for the first time - up to a possible expiry date - without restriction.

The application of the old or new approval law by the manufacturer has no influence on the quality of the medical device.

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