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What is the Medical Device Regulation (MDR)

The Medical Device Regulation (MDR 2017/745) replaces the current EU Directives on Medical Devices (93/42 / EEC) and Active Implantable Medical Devices (90/385 / EEC).

When does the MDR come into force?

The MDR came into force on May 25th 2017.

When do manufacturers of medical devices have to apply the new MDR

The transitional periods are described in Article 120 of the MDR. Accordingly, the MDR becomes applicable on **May 26th, 2020**. From this date at the latest, manufacturers must present an MDR certificate when first placing a product on the market. For all new products and products that will remain Class I even under the MDR, from this date on the MDR will be authoritative.

Will CE certificates that have not expired remain valid after the introduction of the Medical Devices Regulation?

Yes. All CE certificates will continue to be valid until expired or up to five years after application. However, they lose their validity by **May 27th 2024** at the latest.
This means that there is a transition period for medical devices of Class II, which have been certified under the Medical Device Directive, maximally until **May 26th 2024**. Note: The transitional period always depends on the duration of the manufacturer's CE certificate.
In early December 2019, the Committee on the Environment, Public Health and Food Safety of the European Parliament in Brussels approved the second corrigendum to the EU MDR. Accordingly, Class I medical devices that under the MDR require a notified body and for which a declaration of conformity according to the Medical Devices Directive (MDD) was issued before May 26th, 2020, may continue to be placed on the market until May 2024.
The so-called "sell-off clause" for directive-compliant products according to MDR Article 120 IV is also important: Accordingly, the last day for the provision of such medical devices is May 27th, 2025.

Under what conditions may products certified according to the MDD continue to be placed on the market after entry into force of the MDR

- If the devices still meet the requirements of the MDD
- There must be no significant changes in the design and purpose of the products

› However, the requirements of MDR for post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are valid instead of the corresponding requirements of EU Directive 93/42/EEC

What are the most important MDR changes for medical device manufacturers?

Some of the most important changes are:

› Higher classification of medical devices by risk, duration of contact and invasiveness. MDR encourages medical device manufacturers to review the new classification rules and to update their technical documentation accordingly
› Substantially expanded general safety and performance requirements (previously general requirements)
› Additional documentation requirements such as Post Market Surveillance Plan / Report (PMS), Post Market Clinical Follow Up (PMCF), Periodic Safety Update Report (PSUR)
› Medical device manufacturers must designate at least one qualified person in the company who must have qualified expertise in the field of medical devices
› Introduction of UDI labeling to improve the traceability of medical devices
› New regulation of market surveillance with shorter reporting deadlines
› Grandfathering is not intended: All currently certified medical devices must be re-certified to meet the new requirements

What are the most important MDR changes for distributors?

General obligations of distributors are described in Article 14 of the MDR. Using a sampling method which is representative of the devices supplied, the distributor should check whether the device has been CE marked and that the EU declaration of conformity of the device has been drawn up. Furthermore, the distributor should check that the device is accompanied by the information to be supplied by the manufacturer and, where applicable, an UDI has been assigned. In addition, Article 14 describes further obligations for handling non-compliant devices, reporting obligations to manufacturers and authorities, and documentation requirements for complaint management.

What changes do occur in reference to notified bodies?

All notified bodies must be re-accredited by the local authorities under the new MDR for their tasks. It is expected that a significant number of notified bodies may not be renamed again or to the same scope, which might force some medical device manufacturers to change their notified bodies.

What does the new regulation mean for private labels?

The previous PLM / OEM constellations are no longer accepted by the Notified Bodies. Following legally compliant concepts arise for the future cooperation:

› **DETAX Standard products:**
The manufacturer provides you with its original product. Then, you are the distributor of our standard product.

› **Co-branding („Made by“ variant):**
You act as a distributor, importer or re-packer of products and distribute the products with your design. The name of the manufacturer of the products can also be seen on the label. This requires a Quality Assurance Agreement (QAA) between you and the manufacturer for the cooperation, which regulates, among other things, the obligations of the distributor and the traceability of the products.