TÜVNORD

Inspired by Knowledge

MDR: Medical Device Regulation (EU) 2017/745

In May 2021, the MDR (Medical Device Regulation) replaced the Medical Device Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). TÜV NORD CERT GmbH was assessed by a European Joint Assessment Team – with success: Notified Body status was granted on 30.11.2021

During the assessment, particular recognition was given to the high level of competence of the TÜV NORD auditors and experts involved. The MDR describes the legal and regulatory requirements in Europe and has been mandatory since 26 May 2021 for all those who place medical devices on the market in the EU, e.g. for manufacturers and authorized representatives, and for distributors and importers.

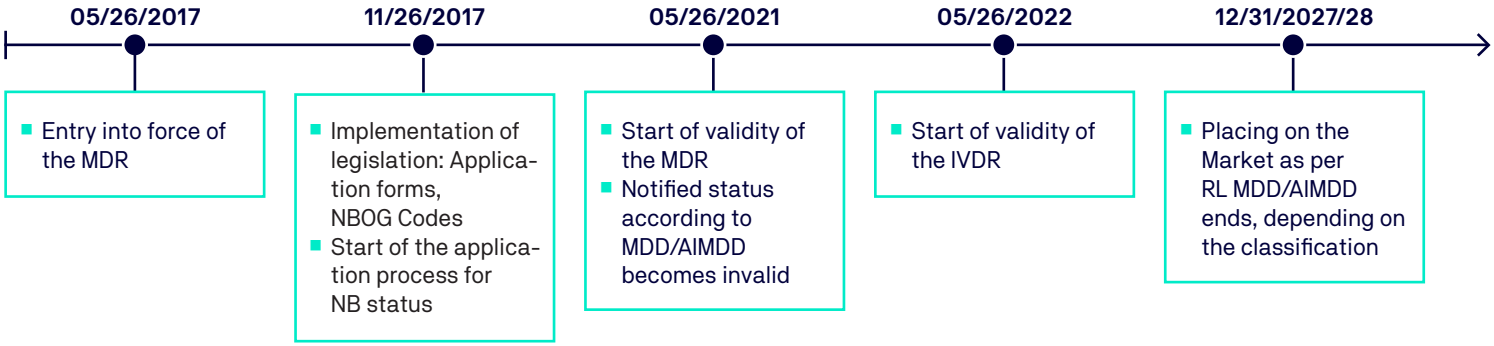
The transitional regulations for medical devices with existing MDD/AIMDD certificates are defined in Article 120 of the MDR.

The new requirements according to Annexes I to VI of the MDR lead to significantly increased and demanding documentation and verification requirements, and Annexes IX-XI concern demanding regulatory requirements for QM systems for medical devices.

The IVDR (In Vitro Diagnostic Regulation) 2017/746 is the EU's new regulation for in vitro diagnostic medical devices. TÜV NORD CERT GmbH has already applied for designation as a notified body for the IVDR, with the assessment process already initiated.

The most important changes for manufacturers of medical devices based on the new MDR

- PSUR – Periodic Safety Update Report (Article 86)
- SSCP – Summary on Safety and Clinical Performance (Article 32)
- UAA – Unannounced Audits (Annex IX 3.4)
- Sampling from the market, product testing, balancing of manufactured product quantities (Annex IX 3.4, 3.5, 4.3)
- Application Assessment (Annex VII Part 4, Annex IX 2.1)
- Recertification – Special Requirements: Summary of Changes, Summary of Scientific Evidence (Annex VII 4.11)
- Consultation procedures with public authorities for specific devices (Article 54)
- New classification, new classification rules, e.g. I(r) (Article 52)
- Registration: EUDAMED, SRN Single Registration Number
- Labelling: Basic UDI (Unique Device Identification) (Article 33, Annex VI)
- Stricter rules for changes (Annex VII 4.9)
- Adoption of common specifications (Article 9)
- A quality management system according to MDR must be implemented by 05/26/2024 at the latest.
- An MDR contract with a notified body must be in place by 09/26/2024 at the latest.



Our know-how for your success

TÜV NORD CERT is an internationally recognized and reliable partner for testing and certification services. Our experts and auditors have in-depth knowledge and generally have a permanent position at TÜV NORD. This ensures independence and neutrality as well as continuity in serving our customers. The benefit to you is clear: our auditors accompany and support the development of your company and provide you with objective feedback.

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