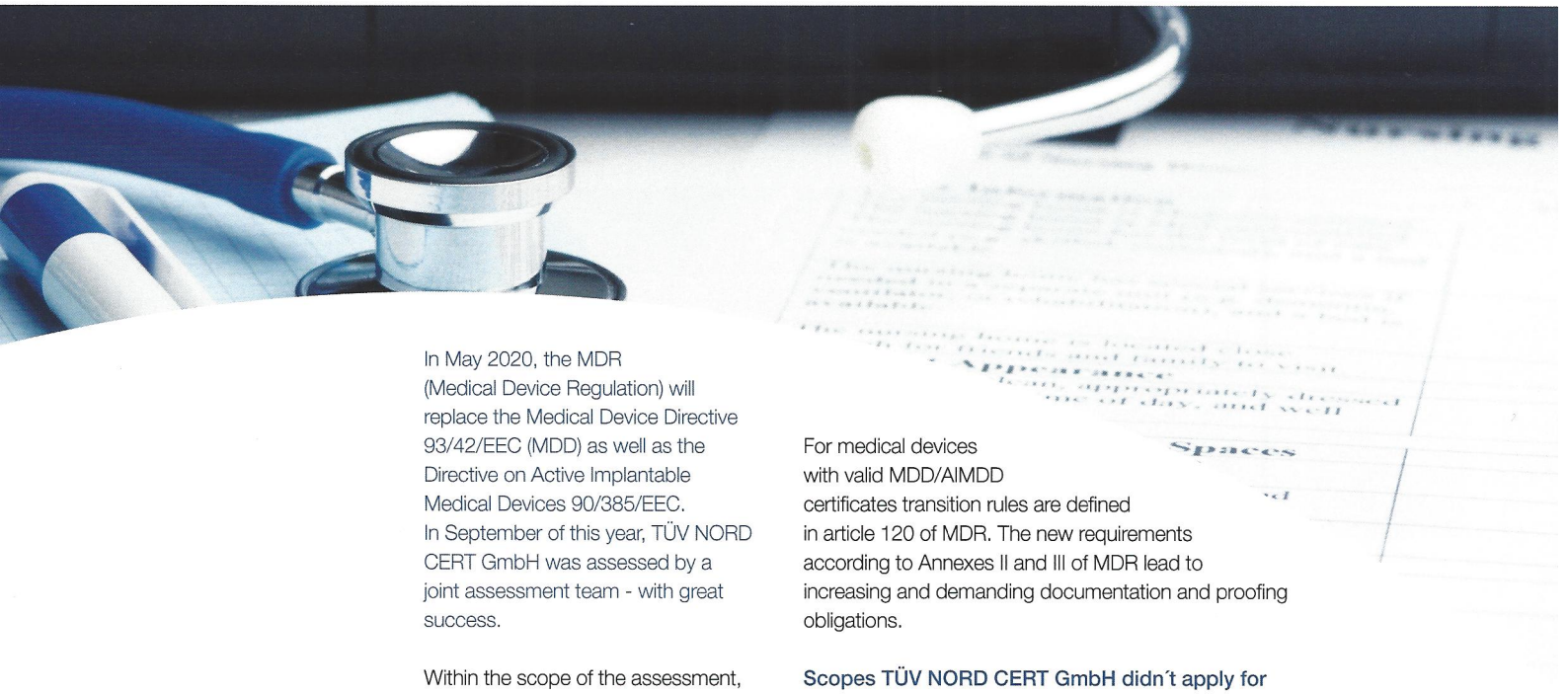
Fact Sheet

TÜV NORD CERT – MDR (Medical Device Regulation), Regulation 2017/745/EU



In May 2020, the MDR (Medical Device Regulation) will replace the Medical Device Directive 93/42/EEC (MDD) as well as the Directive on Active Implantable Medical Devices 90/385/EEC. In September of this year, TÜV NORD CERT GmbH was assessed by a joint assessment team - with great success.

Within the scope of the assessment, the high degree of competence of our auditors and experts was particularly emphasized. In addition, it should be noted that the Medical Device Team continues to work successfully in the direction of designation under regulation 2017/745/EU (MDR). (MDR). The MDR is mandatory from 26 May 2020 for all medical devices that should be placed on the European Market.

For medical devices with valid MDD/AIMDD certificates transition rules are defined in article 120 of MDR. The new requirements according to Annexes II and III of MDR lead to increasing and demanding documentation and proofing obligations.

Scopes TÜV NORD CERT GmbH didn´t apply for

MDA 0101/0102/0103/0104/0303/0304/0314, MDN 1212, MDS 1002/1003/ 1008/1012/1013, MDT 2009

The IVDR

The IVDR (In Vitro Diagnostics Regulation) is the new EU regulation for in vitro diagnostic medical devices. It replaces the current directive for in vitro diagnostic medical devices (98/79/EEC). TÜV NORD CERT GmbH will start a project to apply for notification for IVDR as soon as the MDR accreditation has been successfully completed.

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The most important changes for the manufacturer of Medical products by the new MDR

- PSUR – Periodic Safety Update Report (Art 86)
- Clinic: SSCP – Summary on Safety and Clinical Performance (Art. 32)
- UAA – Unannounced Audits (Ann IX 3.4)
- Testing (Ann IX 3.5, 4.3)
- Application Review (Ann. VII part 4, Ann IX 2.1)
- Recertification – special requirements: e.g. Summary of changes, Summary of scientific findings (Ann. VII, 4.11)
- Scrutiny (Art. 54)
- New classification new classification rules: e.g. I(r) (Art 52)
- EUDAMED (e.g. SRN Single Registration Number, Basic UDI Unique Device Identification) (Art. 33, Ann VI)
- Timelines: e.g. audits each 12 months, reporting to MDCG
- Stricter rules for changes (Ann VII 4.9)
- Use of Common Specifications (Art. 9)

26.05.2017	26.11.2017	26.05.2020	26.05.2022	26.05.2024	26.05.2025
Entry into force of MDR	■ implementing acts (e.g. NBOG Codes) ■ start of application for designation of Notified Bodies	■ Date of application of MDR ■ Notifications acc. to MDD/AIMDD become void	■ Date of application of IVDR ■ Notifications acc. to IVDD become void	Last date for placing products on the market under MDD/AIMDD	Last date for making available or putting into service of devices already placed on the market under MDD/AIMDD

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