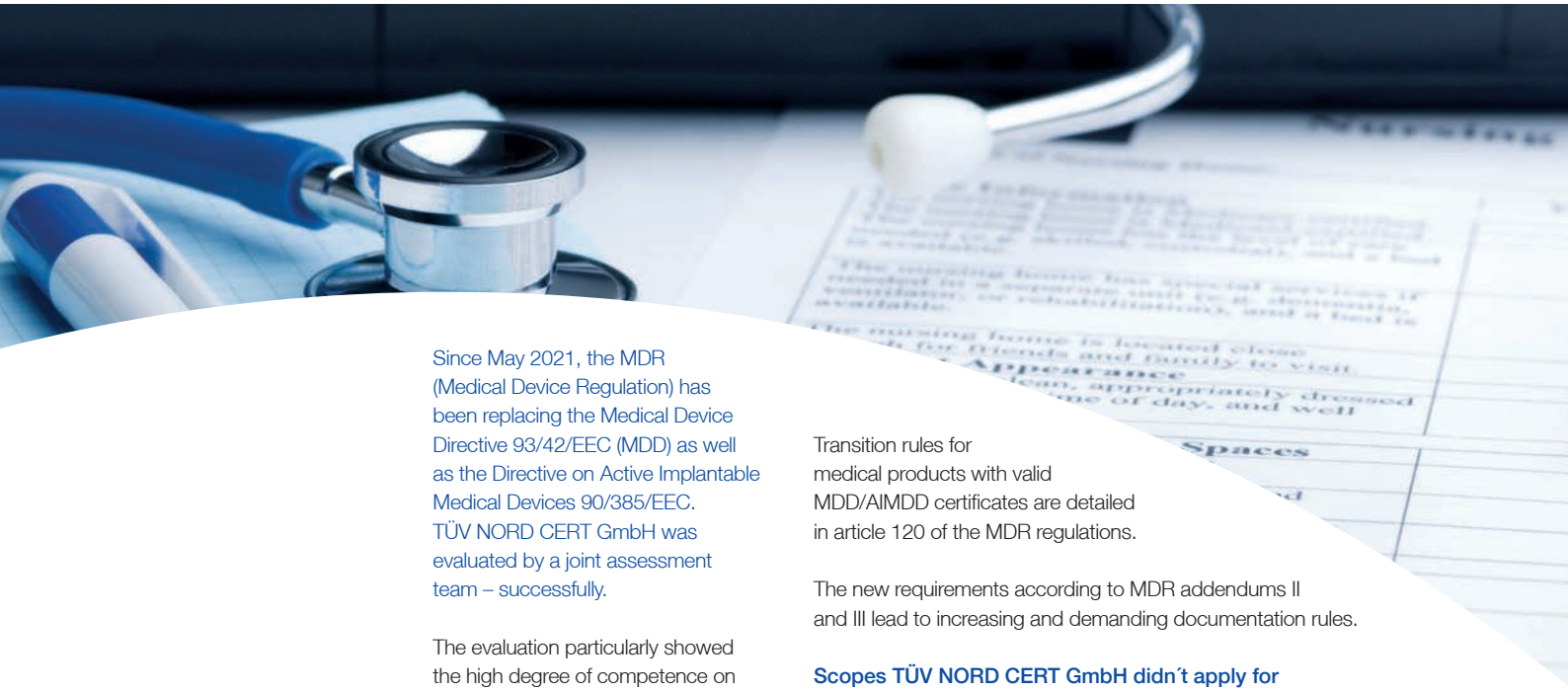
Fact Sheet

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



Since May 2021, the MDR (Medical Device Regulation) has been replacing the Medical Device Directive 93/42/EEC (MDD) as well as the Directive on Active Implantable Medical Devices 90/385/EEC. TÜV NORD CERT GmbH was evaluated by a joint assessment team – successfully.

The evaluation particularly showed the high degree of competence on the part of our auditors and experts. The nomination for (EU)2017/745 is expected shortly.

MDR regulations are mandatory for all medical devices as of May 26, 2021

Transition rules for medical products with valid MDD/AIMDD certificates are detailed in article 120 of the MDR regulations.

The new requirements according to MDR addendums II and III lead to increasing and demanding documentation rules.

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 has already applied for IVDR accreditation, and the review process has been initiated.

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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	26.05.2021	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

Are you interested?
Please send us your response by e-mail.
We are looking forward to hearing from you.

☐ **Yes, I am interested in the Medical Device Regulation. Please contact me.**

☐ **I would like to be informed about current issues in the future via newsletter.**

I would like to go straight to newsletter subscription ▶

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TÜV NORD CERT GmbH
Tel.: 0800 245-7457 (Service-Hotline free of charge)
medical@tuev-nord.de

You can find further information and our subsidiaries at
www.tuev-nord-cert.com

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