

Press Release



Add value.
Inspire trust.

Extended scope strengthens market access for medical devices in Europe

June 16, 2026

TÜV SÜD Notified Body 2443 with Substantially Broadened Scope of Designation under MDR 2017/745

Copenhagen/Munich. On 16 June 2026, TÜV SÜD Danmark ApS received its extended designation from the Danish Medicines Agency (DKMA) under the Medical Device Regulation (EU) 2017/745, with a substantially broadened scope that now includes all MDR device codes except those relating to reprocessing. With this enhanced conformity assessment offering, Notified Body 2443 demonstrates its commitment to supporting manufacturers efficiently and effectively in gaining access to the European market.

Notified Body 2443 is an independent legal entity within the global TÜV SÜD Medical & Health Services (MHS) business unit, headquartered in Copenhagen. It belongs to TÜV SÜD AG, a testing, inspection and certification service provider with long-standing experience in ensuring the safety, security and market access of medical devices and IVDs. With this enhanced designation, Notified Body 2443 (NB 2443) can now assess and certify medical devices across most device areas, including products involving in-vitro fertilisation (IVF), ionising and non-ionising radiation, wound and skin care products, ophthalmic and dental products, and cleaning, disinfection and rinsing devices, and products without a medical purpose in accordance with the MDR 2017/745.

Initially designated in April 2024, NB 2443 specialised in conformity assessments of innovative cardiology, neurology, orthopaedic and software-based medical devices. It delivered MDR certificates for Class IIa, IIb and Class III products with a highly competitive turnaround time from application to issuance of the certificate. This enhanced regulatory expertise, which covers all MDR 2017/745 codes, except reprocessing, grants manufacturers extended access to end-to-end regulatory conformity assessment when preparing their medical devices for entry into the European market.

“With DKMA now granting TÜV SÜD NB 2443 a significantly increased designation scope, the European MedTech ecosystem gains a strategic advantage in sustaining its competitiveness,” says Andreas Stange, Senior Vice President Medical & Health Services at TÜV SÜD. “Our aim is to translate regulatory requirements into transparent, consistent and predictable certification

processes for medical device innovators and manufacturers. With an average timeline of under six months from application to EU certificate issuance, customer promoter scores and testimonials demonstrate our ability to deliver reliably and efficiently through our unique operating model.”

Martin Jakobsson, Vice President Medical Health Services Northern Europe and Vice President of TÜV SÜD Danmark MHS, adds: “DKMA’s commitment and cooperation has been highly valuable to us in obtaining this enhanced designation. NB 2443 delivers predictability and transparency in our price structure and throughout the entire MDR 2017/745 conformity assessment process. We are ready and committed to helping strengthen Europe’s attractiveness for global MedTech investments and innovative products.”

With the extended designation, TÜV SÜD confirms its market position as a global companion for the medical device manufacturers, offering clients a smooth onboarding process for their projects and a consistent, transparent and predictable customer experience.

About TÜV SÜD Medical & Health Services

TÜV SÜD’s global Medical & Health Services business unit supports manufacturers of medical devices and in vitro diagnostics with testing, inspection and certification services throughout the entire product life cycle. It was one of the first organisations worldwide to be designated under MDR 2017/745, and it has continuously expanded its capacities in recent years. More than 1,100 experts at over 30 locations worldwide support manufacturers with regard to safety, quality and international market access.

Further information:

- [NANDO Notification Details](#)
- [Medical Device Regulation \(MDR\)](#)
- [TÜV SÜD Denmark](#)

Note for editorial staff: The press release is available on the Internet at:

tuvsud.com/newsroom.

Media Relations

TÜV SÜD Public Relations Westendstraße 199 80686 Munich, Germany	Dirk Moser-Delarami Phone +49 89 5791-1592 Email dirk.moser-delarami@tuvsud.com Internet tuvsud.com/newsroom
---	---

Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. Around 30,000 employees work at over 1,000 locations in about 50 countries to continually improve technology, systems and expertise. They contribute significantly to making technical innovations such as Industry 4.0, autonomous driving and renewable energy safe and reliable. tuvsud.com