

Press Release



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With a focus on cardio, neuro, orthopedic and software innovations

6 April 2024

TÜV SÜD Danmark ApS receives designation as Notified Body in accordance with MDR 2017/745

Copenhagen/Munich. TÜV SÜD Danmark ApS today received its designation as Notified Body 2443 under Medical Device Regulation 2017/745 by the Danish Medicines Agency (DKMA). Notified Body 2443 is a separate legal entity within TÜV SÜD AG.

Headquartered in Copenhagen, Denmark, it forms part of the global business unit Medical & Health Services (MHS). MHS' core business involves supporting medical device and IVD manufacturers by providing testing, inspection and certification services, thereby ensuring the safety, security and market access of medical devices and IVDs.

With this additional Notified Body under MDR 2017/745, TÜV SÜD is extending its capabilities and knowledge with a team of experts located across the globe. The highly customer centric approach is mirrored in every step of its tailor-made quality management system, geared to delivering an efficient conformity assessment process while lowering complexity. NB 2443 focuses on business areas such as cardio, neuro, orthopedic and software innovations and supports companies of all sizes, from SME's to larger-scale organisations. The team is starting from scratch; free from the responsibility for an existing certificate portfolio, it can therefore devote its full abilities and commitment to efficiently and predictably delivering market certification for MDR innovative devices.

The transition from MDD to MDR has been a challenge for all stakeholders. At the same time, the Notified Bodies have repeatedly been placed under strain. Since the MDR came into effect, the demand for more Notified Body capacity has grown significantly. However, TÜV SÜD has built up these capacities early and continuously and, with the new Notified Body in Denmark, is now covering additional current and future needs.

Dr Royth von Hahn, Global Senior Vice President Medical & Health Services at TÜV SÜD, says: "We are very happy about the designation of our Danish MDR Notified Body. It is an excellent example of how TÜV SÜD is investing in additional Notified Body resources, thereby demonstrating responsibility and commitment to the European Medical Device market. Through this designation, we are opening up an additional pathway for innovative medical device manufacturers to enter the European market, which will help to ensure that their devices are placed on the EU market as early as possible."



MHS of TÜV SÜD in Denmark features a unique quality management system tailored to MDR requirements, as Martin Jakobsson, Vice President Medical & Health Services TÜV SÜD Danmark ApS, explains. "The efficiency and effectiveness in how we deliver services to our clients is what makes us unique. We want our clients to benefit from solid predictability, a high degree of transparency and consistency at all touchpoints throughout the entire conformity assessment process." This is also reflected in the team structure that TÜV SÜD has built and in its on-going recruitment of top-notch experts, drawing on their vast experience within the industry and with Notified Bodies. The structure is designed to work in high-performing project teams tailored around individual manufacturers' conformity assessment needs and timelines for their specific innovative medical devices. Martin Jakobsson summarises, "Our customer journey is uniquely mapped to reduce complexity, from pre-application to certification. We are here to enable innovative medical devices to access the EU market first."

1,200 medical device experts at over 30 locations

TÜV SÜD's global business unit Medical & Health Services (MHS) was one of the first organisations worldwide to be approved under MDR 2017/745. MHS has also steadily built capacity over the past five years (CAGR of almost 20 %) and is present with more than 1,200 medical device experts at over 30 locations worldwide – and now also with its additional Notified Body in Denmark.

More information can be found at www.tuvsud.com/dk and www.tuvsud.com/mdr.

Note for editorial staff: The press release and high-resolution photos are available on the internet at www.tuvsud.com/newsroom.

Media Relations:

TÜV SÜD AG Corporate Communications Westendstr. 199 80686 Munich, Germany	Dirk Moser-Delarami Phone +49 89 5791-1592 E-Mail dirk.moser-delarami@tuvsud.com Internet tuvsud.com/newsroom
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Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. More than 26,000 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