



Press Release

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Premiere for the new Notified Body 2443

8 October 2024

TÜV SÜD Danmark ApS issues first MDR certificate

Copenhagen/Munich. On 7th October 2024, the Notified Body TÜV SÜD Danmark ApS (NB 2443) has issued its first certificate in accordance with MDR 2017/745, to a customer manufacturing a medical device that can automatically perform standardized neuro-ophthalmic tests.

TÜV SÜD Danmark ApS (NB 2443) is proud to announce that it has issued its first certificate according to MDR 2017/745. The certification was granted to a European customer manufacturing a medical device that can automatically perform standardized neuro-ophthalmic tests to support clinical decision making.



Malou Hjæresen, Head of Certification at TÜV SÜD Denmark MHS, and the dedicated project team enjoyed working on TÜV SÜD's first customer case: "Tackling the complexity of medical device compliance for the novel device has been challenging and rewarding. Thanks to effective project management, our dedicated team of software and medical device experts could focus on completing their tasks on time and as required."



Martin Jakobsson, Vice President of TÜV SÜD Denmark MHS, sees the operational set-up confirmed: "This first certificate demonstrates that we deliver on our promises. TÜV SÜD provides predictability and transparency for the customer from pre-application to certificate, both in terms of timelines and the fixed pricing. Our Notified Body is open for clients who need to file a new application in accordance to MDR 2017/745 for their products and want to avoid waiting times."

Notified Body 2443 was designated in accordance with MDR 2017/745 on April 6, 2024 by the Danish Medicines Agency (DKMA). TÜV SÜD with its Notified Bodies (0123 and 2443) covers the full scope of the MDR and supports companies of all sizes from SMEs to larger-scale organizations. Both Notified Bodies are managed within the MDR portfolio of TÜV SÜD AG

and are thus part of the globally operating Medical & Health Services (MHS) business unit and has specialised expertise in innovative cardiological, neurological and orthopaedic medical devices, as well as software innovations.

The MHS business unit supports medical device and IVD manufacturers by providing testing, inspection, and certification services, thereby ensuring the safety, security, and market access of medical devices and IVD medical devices.

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

Note for editorial staff: The press release and high-resolution photos are available on the internet at tuvsgd.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. About 28,000 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. tuvsgd.com