Press Release

Add value.
Inspire trust.

12 July 2024

TÜV SÜD awards one of the first certificates based on Annex XVI of EU Regulation 2017/745 to DEKA

Milan/Florence. TÜV SÜD, one of the world's leading certification companies, has granted DEKA M.E.L.A., Italy's leading manufacturer of laser devices for medical and non-medical applications, MDR (Medical Device Regulation) certification for its products. DEKA is one of the first active medical device manufacturers in the world to also manufacture products with non-medical intended use and has received this certification from TÜV SÜD.

DEKA is an international company, part of the El.En. Group, and manufactures technologically advanced laser devices for both medical and non-medical use. The new MDR certification, obtained according to Annex XVI which includes products without a medical use, testifies the conformity of DEKA's products and ultimately their quality and safety. The devices in question have been included in EU Reg. 2017/745 as they are similar to medical devices in terms of function and risk profile, and therefore must demonstrate compliance with the 'Common Specifications' (CS). The certification process, led by TÜV SÜD's Italian Team, demonstrated the compliance of DEKA Laser devices with the European regulations.

"We are very pleased to be able to issue DEKA Laser this important Certificate in accordance with the requirements of Annex XVI of EU Reg. 2017/745," underlines Loris Chiusoli, Business Unit Manager MHS of TÜV Italia. "This formal recognition is a firm testimony to DEKA's professional commitment, which TÜV SÜD was able to experience during the project. Special thanks go to the Italian TÜV SÜD Team, who managed this project flawlessly."

He is echoed by Ing. Paolo Salvadeo, Managing Director of DEKA and General Manager of the holding company El.En. SpA: "The extremely hard work of our Project, Quality, and

Regulatory Teams, who were in constant technical dialogue with the TÜV SÜD experts, led to the achievement of the important MDR certification of many of our flagship devices. Needless to deny the difficulty in achieving this very stringent goal, but this is not the first time DEKA has been a pioneer. It has demonstrated this with all the innovations that have characterised its activities over more than 30 years of history, and now in achieving this important project. On its part, TÜV SÜD succeeded brilliantly in untangling the intricacies of the European standard, and DEKA adapted its products and standards in the direction of achieving the goal.I am fully satisfied".

Caption: Award ceremony of the MDR certificate for non-medical purposes.

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

Media Relations:

Dirk Moser-Delarami TÜV SÜD AG Corporate Communications Westendstr. 199, 80686 Munich	Phone +49 (0) 89 / 57 91 – 15 92 Fax +49 (0) 89 / 57 91 – 22 69 Email dirk.moser-delarami@tuvsud.com Internet www.tuvsud.com

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. tuvsud.com