



One-stop testing from TÜV SÜD

20 July 2020

Extensive range of medical device testing from a single source

Munich. Medical devices often need to fulfil a variety of different requirements simultaneously. TÜV SÜD acts as a one-stop shop for testing medical devices, offering a comprehensive portfolio of services that spans physical, electrical, biological and chemical testing as well as cybersecurity testing.

“Medical device manufacturers are increasingly seeking to access a full range of testing services from a single source,” says Klaus Schlicht, Vice President Global Testing Medical & Health Services at TÜV SÜD Product Service GmbH, commenting on TÜV SÜD’s uniquely advantageous position on the testing market. One reason for this could be the extremely dynamic nature of the medical device market, where ever shorter lead times are a must if new products are to be successful as technical innovations. Testing needs to cover not only physical characteristics, but also biological and chemical properties plus IT security. In addition, products must conform to the stringent requirements set forth in regionally varying standards.

One-stop testing opens the door to faster market access

TÜV SÜD’s single-source testing services speed up market access for medical devices by serving as a one-stop shop that provides the full scope of tests necessary for compliance with national regulations. This lowers project and product risks while simultaneously reducing development costs. Physical testing includes electrical safety and electromagnetic compatibility as well as tests simulating the wide variety of environmental impacts that may affect the product itself and its packaging sterility during transport, storage and operation. The portfolio of biological and chemical services includes aspects such as chemical characterisation, microbiology and sterilisation behaviour and also extends to validation of biocompatibility to rule out negative effects on humans. IT security testing may involve vulnerability scans or penetration testing.

TÜV SÜD P.H. with ISO accreditation for medical device testing

At the end of May the P.H. laboratory in Italy received accreditation for nine methods of chemical characterisation. Auditors from Accredia, the Italian accreditation body, performed the audit as a remote procedure in line with the restrictions imposed to combat COVID-19. P.H. is now one of just a handful of laboratories in Italy that holds accreditation for medical device testing. The laboratory will also gain the status of “European Lab Hub for biological / chemical testing of medical devices” and will thus supply all European customers with chemical characterisation and in-vitro biocompatibility tests in future.

Global presence

TÜV SÜD Product Service has over 30 years of experience in medical device testing, certification and approval and in dealing with regulatory requirements for a host of different markets. The company’s aim is to provide guarantees of the safety, quality and sustainability of medical products and their successful placement on the market. Operating a global network of accredited testing laboratories, TÜV SÜD is regarded as the leading service provider for the medical device industry.

New webinar on test procedures: “Medical Device Testing for Biocompatibility – Requirements of MDD and MDR”

A critical step in manufacturing medical devices involves the process of transforming an innovative design into a reliable, marketable product. TÜV SÜD expert Dr Christoph D. Lindner will provide information on the numerous tests which medical device manufacturers must undergo and the testing requirements under the MDD (Medical Device Directive) and MDR (Medical Device Regulation), focusing particularly on the ISO 10993 family of biocompatibility standards. The webinar, which will be held in English, will explain various tests including biocompatibility and chemical tests as well as package validation tests, and will examine transport simulation, durability standards and product-specific standards.

Date: 21 July, 10 am – 11 am (MEST)

For further information on TÜV SÜD’s portfolio of medical device testing services, visit

<https://www.tuvsud.com/en/industries/healthcare-and-medical-devices>

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