Press Release

TÜV SÜD to take part in online trade show and congress 6 April 2021

At MedtecLIVE as one-stop shop for medical device-related services

Munich. TÜV SÜD will present itself at this year's MedtecLIVE as a one-stop shop for medical device testing services. The company's services cover testing in the areas of electrical and functional safety, cybersecurity and software, EMC and biocompatibility. The experts from TÜV SÜD will be featured in the programme of the online trade show and congress with various talks, a live hack and an elevator pitch. The virtual meeting-point for medtech developers and manufacturers will be online from 20 to 22 April.

"Medical technology has to meet ultra-rigorous quality standards as well as delivering cost-effectiveness and minimising time to market", says Norbert Stuiber, Director Global Sales & Strategic Marketing at TÜV SÜD. "Our experts will use the MedtecLIVE chat function and live video meetings as a platform for discussing various topics, including aspects of the Medical Device Regulation that are of relevance to manufacturers and issues concerning approval." Although the date of application of the Medical Device Regulation (MDR) has been postponed to this May, some manufacturers are still unaware of the General Safety and Performance Requirements (GSPR) which apply to the Regulation and with which their products must conform, such as proof of biocompatibility following a risk-based approach in line with ISO 10993.

Wireless technology is gaining ground

Further new regulations have been established in response to the spread of wireless technologies, which are governed by the MDR, but also by national standards and radio communication laws including the EU RED (Radio Equipment Directive, 2014/53/EU) and the requirements of FCC/ISED in the USA and Canada, MIC in Japan and ANATEL in Brazil. In some cases, medical device manufacturers prefer to make use of devices that are already tested and certified instead of developing their own wireless modules. While this approach saves time and costs, it requires precise instructions from the module manufacturer. "Developers must be familiar with the regulatory requirements of the markets in question; all technical and legal aspects – such as permissible frequency bands for local operation – must be clarified prior to installation", warns Thomas Ring, Senior Account Manager Global Wireless Approvals.

“To ensure national approval applications are successful, companies must take action at an early stage and ensure they can furnish seamless end-to-end documentation.”

TÜV SÜD talks and events in the MedtecLIVE programme

- Talk – “Experience from the First MDR Audits – Common Pitfalls for Manufacturers”, Dr Christiana Hofmann, Team Lead Non-Active Medical Devices (20 April 2021, 10:50-11:15 am)
- Elevator Pitch – “Testing Services – TÜV SÜD as One-Stop Shop” (20 April 2021, 1:04:00-1:05:30 pm)
- Talk – “Prüfung von Medizinprodukten für Biokompatibilität – Anforderungen der MDR” [Biocompatibility Testing of Medical Devices – MDR Requirements], Christoph D. Lindner, Medical Device Testing Expert (20 April 2021, 1:30-1:45 pm)
- Talk – “Wireless goes global – Internationale Zulassungen von Medizinprodukten mit Wireless-Funktionalität” [Wireless Goes Global – International Approval of Medical Devices with Wireless Functionality], Thomas Ring, Senior Account Manager Global Wireless Approvals (21 April 2021, 1:00-1.20 pm)
- Live Hack – hacking a simulated medical device, with Sourabh Naik, Cyber Security Expert (22 April 2021, 3:55-4:05 pm)
- Talk – “Cybersecurity for Medical Devices”, Jan Küfner, Senior Product Specialist Cyber Security (22 April 2021, 4:05-4:30 pm)

About MedtecLIVE

The must-attend event in the international medical technology calendar is a virtual platform providing an overview of new developments and innovations. The exhibitors are joined by attendees ranging from suppliers, manufacturers and developers to scientists and researchers. Topics addressed at the event cover IT, materials and components and related activities as well as products and services.
www.medteclive.com

About TÜV SÜD

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 devices 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.

https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification

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