



Digital Dialogues from 3 to 5 November 2020

22 October 2020

3-day TÜV SÜD webinar series on MDR, IVDR and testing

Munich. In the unprecedented events related to the coronavirus pandemic over recent weeks and months, TÜV SÜD has also been challenged to rethink the methods and forms of communication it uses for exchanges of ideas and experience with experts, and to explore new avenues in this direction. TÜV SÜD has now developed Digital Dialogues, an innovative digital format that offers direct access to the consolidated knowledge of TÜV SÜD experts while optimising participants' time and effort. Digital Dialogues will be held from 3 to 5 November in English.

Over the three days, TÜV SÜD will present a series of webinars on issues related to the Medical Device Regulation (MDR), In-vitro-Diagnostic Regulation (IVDR) and testing. After all, medtech questions related to testing, certification and approval are best clarified directly in face-to-face meetings with experts in the field. TÜV SÜD's global network, comprising medical doctors, experienced engineers, chemists and biologists, offers significant added value on the international medtech market. On all three days, participants also have the opportunity to book one-to-one meetings with our experts to address individual concerns and questions.

On each of these three days, the webinar series will offer several online presentations. The presentations will be held once in the morning from 8:30 am CET and once in the afternoon from 4:30 pm CET, to maximise planning flexibility for the participants.

The programme of the 3-day webinar series is as follows:

3 November: Testing

The first day of our Digital Dialogues event will focus on the testing of medical devices. The programme covers topics such as cybersecurity, biocompatibility testing, the 60601-1 standard, electromagnetic compatibility and the special requirements for medical devices with wireless functionality.

8:30 am and 4:30 pm CET – Francisco Navarro: Cybersecurity for Medical Devices

9:30 am and 5:30 pm CET – Dr Christian D. Lindner: Medical device testing for biocompatibility – MDD and MDR requirements

10:30 am and 6:30 pm CET – Dr Tobias Beck: Testing in accordance with the IEC 60601-1 series for Active Medical Devices

11:30 am and 7:30 pm CET – Hannes Adelsberger: Medical Device Testing for EMC/radio compliance – Requirements of MDR and RED

4 November: MDR

Day two in our webinar series is dedicated to the current Medical Device Regulation. The Medical Device Regulation (MDR) presents quite an extensive list of requirements for manufacturers. TÜV SÜD specialists shed light on the MDR and the requirements specified therein.

8:30 am and 4:30 pm CET – Martin Witte: Technical Documentation under MDR

09:30 am and 5:30 pm CET – Robert Madjno: Understanding Clinical Data under the MDR

10:30 am and 6:30 pm CET – Dr Julia Hoyer: MDR lessons learnt

11:30 am and 7:30 pm CET – Dr Sabine Hoekstra: MDR additional authority consultation procedures

5 November: IVDR

The regulation on in-vitro diagnostic medical devices (IVDR) is on the agenda on day three of the webinar series. Which standards must be complied with by manufacturers? What must be considered in the preparation of Technical Documentation? How does testing work? The webinars will give answers to these and many other relevant questions associated with the IVDR.

8:30 am and 4:30 pm CET – Marta Carnielli: Technical Documentation under the IVDR

09:30 am and 5:30 pm CET – Dr Thomas Theisen: Clinical evidence in IVDR Technical Documentation

10:30 am and 6:30 pm CET – Dr Alexander Stock and Martin Heinrich: IVD Equipment Testing – Software & Electrical Safety

11:30 am and 7:30 pm CET – Marta Carnielli: IVD classification under the IVDR

Further information and registration for the Digital Dialogues at : <https://www.tuvsud.com/en/resource-centre/webinar/digital-dialogues>

Note for editorial staff: The press release can be downloaded from www.tuvsud.com/newsroom.

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