Press Release

Digital Dialogues Vol. 2 from 17 to 20 May 2021 3 May 2021

TÜV SÜD continues its successful live webinar series on MDR, IVDR and testing services

Munich. When the first TÜV SÜD Digital Dialogues were planned and held last year, the event organisers could not have predicted that the continuing Covid-19 pandemic would force this year's event to keep the digital-only format – or how enormously popular this format would become. Given this, TÜV SÜD decided to launch Volume 2 of the Digital Dialogues. From 17 to 20 May 2021, interested parties can once more directly access the consolidated knowledge of the experts from TÜV SÜD. The testing, inspection and certification organisation is repeating its online format, which fosters exchanges of ideas and experience while optimising participants' time and effort.

Over four days, TÜV SÜD will present a series of 14 different live webinars addressing the most challenging issues of the Medical Device Regulation (MDR), In-Vitro Diagnostic Regulation (IVDR) and testing and certification services. TÜV SÜD's global network, comprising experienced medical doctors, engineers, chemists and biologists, offers significant added value on the international medtech market. From experience, we know that medtech questions related to testing, certification and approval are best clarified directly in face-to-face meetings with experts in the field. Like last year, participants on all four days will again have the possibility to discuss their specific needs and objectives in virtual one-to-one meetings.

Digital Dialogues Vol. 2 is another valuable event for all manufacturers, regulators and quality, product development and IT professionals in the health and medical-device industry who are seeking to drive innovation and lead the market.

On each of its four days, Digital Dialogues Vol.2 will offer several online webinars. To give participants maximum flexibility in their planning, the sessions will be held in the mornings from 8:30 am and repeated in the afternoons from 4:30 pm (CET). All webinars are held in English and are free of charge.

Programme details of the 4-day online event:

17 May: MDR

The first day of the webinar series is dedicated to the highly topical Medical Device Regulation (MDR), whose (extended) transition period is slated to end on 26 May 2021. The MDR continues to present manufacturers and Notified Bodies with a relatively extensive list of requirements. The TÜV SÜD specialists will provide detailed information about the specified requirements.

8:30 am and 4:30 pm Medical device software – Marco Caproni

09:30 am and 5:30 pm Cyber Security – Jan Küfner / Dr Abtin Rad

10:30 am and 6:30 pm Basic UDI-DI from the view of a Notified Body – Julia Hoyer

11:30 am and 7:30 pm Article 117 MDR – Notified Body opinion – Dr Christiana Hofmann

18 May: Testing (Part 1)

Days two and three of the webinar series will focus on the testing of medical devices. The programme covers topics such as GSPR, functional safety, electromagnetic compatibility, environmental simulation, chemical characterisation and MRI.

09:30 am and 5:30 pm MDR Annex I: General Safety and Performance Requirements (GSPR) – Compliance through evidence – Martin Witte

10:30 am and 6:30 pm Functional and single fault safety in medical devices – Alba Marina Malavé Dos Santos und Dr. Abtin Rad

11:30 am and 19:30 pm Medical device testing for radio compliance – Requirements of RED – Matthias Stumpe

19 May: Testing (Part 2)

09:30 am and 5:30 pm Environmental simulation and testing – Wolfgang Jakobi

10:30 am and 6:30 pm Chemical characterisation and the importance of a toxicological risk assessment – Dr Christoph D. Lindner

11:30 am and 7:30 pm MRI – safety of medical devices – Mahdi Abbasi

20 May: IVDR

The Regulation on In-Vitro Diagnostic Medical Devices (IVDR) is on the agenda on day four of the webinar series. Beyond the exchange of experience from first IVDR certification projects, experts will give an overview of the classification rules and the MDCG guidance document and take an in-depth look at possible solutions for fulfilling the requirements and at applicable tests.

8:30 am and 4:30 pm Update on IVDR implementation – Dr Andreas Stange

09:30 am and 5:30 pm IVD classification under the IVDR – Marta Carnielli

10:30 am and 6:30 pm Instruments / Software-specific requirements under IVDR – Dr Julien Senac

Further information and registration for the Digital Dialogues at:

https://www.tuvsud.com/en/events/digital-dialogues

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

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