



Digital Dialogues Vol. 3 from 8 to 12 November 2021

25 October 2021

TÜV SÜD's successful live webinar series on MDR, IVDR and testing goes into the third round

Munich. TÜV SÜD Digital Dialogues, the digital format developed spontaneously by the testing and certification provider in response to the Covid-19 pandemic, has become firmly established as a global platform addressing the safety, security and market access of medical devices and in-vitro diagnostics (IVDs). TÜV SÜD is an important player in the medtech industry and has an in-depth understanding of its current and future opportunities and challenges, among them artificial intelligence (AI), MDR and IVDR. With this in mind, it is now holding Vol. 3 of its Digital Dialogues from 8 to 12 November 2021, entitled “Get ahead with top-tier MedTech and IVD expertise”. By doing so, the company is promoting the exchange of ideas and experience and offering direct access to the consolidated knowledge of the TÜV SÜD experts.

Over the five days, TÜV SÜD will present a strategy forum and a series of 16 different live webinars and hands-on sessions addressing the most challenging issues in the fields of Medical Device Regulation (MDR), In-Vitro Diagnostic Regulation (IVDR) and testing. 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 five days will again have the possibility to discuss their specific needs and objectives in virtual one-to-one meetings.

A new feature of Digital Dialogues Vol. 3 is the “MedTech Strategy Forum”. In this 30-minute kick-off event, the top management of Medical & Health Services at TÜV SÜD will talk about current trends and challenges, giving insights into TÜV SÜD's vision for the medtech market and its position there. A live chat will offer participants the opportunity to ask questions.

Royth von Hahn, Senior Vice President Medical & Health Services: “The ultimate goal is always to improve patients' quality of life. Progress represents the means to this end in the industry, with medical devices and IVD becoming increasingly important. We want to enable companies to get ahead and give

them a lead. With this goal in mind, our Digital Dialogues Vol. 3 is held under the theme of “Get ahead with top-tier MedTech and IVD expertise”.

Digital Dialogues Vol. 3 is a further valuable event for all manufacturers, regulators and quality, approval, product development and IT professionals in the health and medtech industry who are seeking to drive innovation and lead the market.

On each of its five days, Digital Dialogues Vol. 3 will offer a range of online webinars or hands-on sessions. To allow participants maximum flexibility in their planning, the sessions will be held in the mornings from 8:30 am and repeated in the afternoons from 4:00 pm or 4:30 pm (CET) respectively. All webinars are held in English and are free of charge.

Programme details of the 5-day online event:

8 November: MDR

9:00 am and 4:00 pm: **MedTech Strategy Forum** – Dr Royth von Hahn, Dr Tobias Beck, Dr Sabina Hoekstra and Dr Andreas Stange

Following this kick-off event, the first day of the webinar series will again be dedicated to the current Medical Device Regulation (MDR), for which the transition period will end in May. The TÜV SÜD specialists will focus on selected specific requirements from the MDR’s extensive list of requirements, such as the requirements for aesthetic devices or combination products, and will provide updates on topics such as the UKCA marking and change management.

10:30 am and 5:30 pm **ANNEX XVI: Emerging challenges for aesthetic manufacturers** – Dr Melania Battistella / Dr Christiana Hofmann

11:30 am and 6:30 pm **Change management under the MDR** – Dr Michael Binder

12:30 pm and 7:30 pm **UKCA mark update** – Dr Monisha Philipps

9 November: Medical Device Testing (Part 1)

The second and third day of the webinar series will again focus on the increasingly important testing of medical devices. Topics such as market access to the USA/Canada, wireless/radio-specific approval, biocompatibility, accelerated ageing including transport simulation and sterile packaging, and MRI are on the programme.

9:30 am and 5:30 pm **Market access to USA / Canada** – Markus Herrmann, Hannes Adelsberger

10:30 am and 6:30 pm **Wireless / radio-specific approval** – Thomas Ring

10 November: Medical Device Testing (Part 2)

09:30 am and 5:30 pm **Biocompatibility of medical devices – General strategies and common pitfalls** – Dr Christoph D. Lindner

10:30 am and 6:30 pm **Accelerated ageing incl. transport simulation and sterile packaging** – Daria Meusburger, Roberto Singer

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

11 November: IVD Regulation & Testing

The Regulation on In-Vitro Diagnostic Medical Devices (IVDR) is on the agenda on day four of the webinar series. The sessions will cover discussions of the latest regulatory updates, the IVDR conformity assessment and experience gathered from IVDR technical documentation assessments

08:30 am and 4:30 pm **IVDR conformity assessment** – Dr Julien Senac

09:30 am and 5:30 pm **Latest regulatory update | Part 1: General** – Marta Carnielli, Dr Andreas Stange

10:30 am and 6:30 pm **Latest regulatory update | Part 2: CDx, Class D, novel Class C** – James Hewitt, Dr Eric Heilmann

11:30 am and 7:30 pm **Lessons learnt on IVDR technical documentation assessments** – Dr Ines Labugger

12 November: Hands-on sessions

The title says it all on day 5 of the Digital Dialogues Vol. 3: in a hands-on approach, the webinars will show participants how to use the checklists for the assessment of biological safety and the MDR and IVDR application forms.

09:00 am and 4:00 pm **Checklists for biological safety assessments** – Dr Andrea Hemm, Dr Trixi Hollweck, Frank Wirsching, Dr Stefanie Böllner

10:00 am and 5:00 pm **MDR application forms** – Annika Fröhlich, Christian Schröder

11:00 am and 6:00 pm **IVDR application forms** – Annika Fröhlich, Dr Pranav Patel

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.

Media Relations:

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