Press Release

Digital Dialogues – successful format returns from 24 to 27 October 2022 6 October 2022

Fourth round of TÜV SÜD's live webinar series on safety, security and global market access in the medtech industry

Munich. TÜV SÜD Digital Dialogues is an established online event that brings together global experts and industry thought leaders to discuss current challenges facing the medtech industry. As usual, the speakers will address a variety of topics including the Medical Device Regulation (MDR), In-Vitro Diagnostic Regulation (IVDR), cybersecurity, biocompatibility testing, reusable devices and packaging. As an important economic operator in the medtech industry, TÜV SÜD will be hosting this exchange of ideas and experiences from 24 to 27 October with the main theme of global market access (GMA) for medical devices. The event will offer direct access to consolidated expert knowledge.

In the four-day programme, now expanded further, TÜV SÜD will present a strategy forum and a series of 18 different live webinars and hands-on sessions addressing the most challenging issues and updates in the fields of MDR, IVDR, cybersecurity and testing. TÜV SÜD's global network of 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 global market access are best answered directly in face-to-face meetings with experts in the field. Like last year, participants on all four days will thus have the possibility to discuss their specific concerns and objectives in virtual one-to-one meetings.

Digital Dialogues 2022 again addresses all interested 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 through strategies including global market access.

Dr Royth von Hahn, Senior Vice President Medical & Health Services, explains, "As the leading Notified Body for Medical Devices, we offer our Digital Dialogues to support economic operators in the medtech industry, helping them to overcome the current challenges. Ultimately, the testing and certification of

medical devices are always about ensuring patients' safety and quality of life by driving quality and innovation."

As previously, the MedTech Strategy Forum will get the ball rolling at Digital Dialogues 2022. In the first part of this kick-off event, the top management of TÜV SÜD Medical & Health Services will address the new EU Regulations and their impacts on the medtech industry as well as the vision, strategy and position of the testing, inspection and certification (TIC) company on the global market for medical devices and IVD. All participants can ask questions in live chat during and after the panel session. In the second part of the kick-off event, high-calibre executives from medtech manufacturers and consulting firms will debate future developments, innovations and business model transformations in the industry as well as patient safety in the context of innovation.

On each of its four days, Digital Dialogues 2022 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 9 am and repeated in the afternoons from 4 pm (CEST). All webinars are held in English and are free of charge.

Programme details of the 4-day online event (subject to change at short notice):

Monday, 24 October:

- 9 am and 4 pm: **MedTech Strategy Forum**
  Part 1: Panel with Dr Royth von Hahn, Dr Andreas Stange, Julia Hoyer, Dr Tobias Beck & Dr Abtin Rad
- Part 2: Panel with Martin Witte and executives from industry and consulting (9:45 am and 4:45 pm)
- 11 am and 6 pm: **Is MDCG 2022-14 the ultimate solution to solve all the challenges of the MDR transition?** – Martin Witte
- 12 noon and 7 pm: **Appropriate surveillance regarding Article 120 (3) of MDR and Article 110 (3) of IVDR for legacy devices** – Dr Alexandra Seber
- 1 pm and 8 pm: **Information required together with your MDR application (appendix A, B, C) – best practices** – Annika Fröhlich

Tuesday, 25 October:

- 9 am and 4 pm: **What are Notified Bodies (even) thinking?** – Dr Robert Madjno

- 10 am and 5 pm: **Recent experiences planning and remediating chemical characterization studies** – Tyler Hollingshaus & Eric Sussman (MCRA (USA))
- 11 am and 6 pm: **Toxicological risk assessment and medical device biological safety** – Tyler Hollingshaus & Matthew R. Jorgensen (Teleflex)
- 12 noon and 7 pm: **Experiences of a Notified Body on MDR assessment of reusable medical devices** – Dr Johannes König
- 1 pm and 8 pm: **Transport simulation, ageing and sterile barrier system testing** – Daria Meusburger & Wolfgang Jakobi

Wednesday, 26 October:

- 9 am and 4 pm: **Strengthening the science of device processing** – Tyler Hollingshaus & Terra Kremer (Johnson & Johnson)
- 10 am and 5 pm: **The role of IEC 81001-5-1 in cybersecurity** – Jan Küfner
- 11 am and 6 pm: **A guide to defend your medical device against cyberthreats** – Jan Küfner
- 12 noon and 7 pm: **Requirements on wireless communication for IoMT devices (Internet of Medical Things)** – Thomas Ring & Matthias Stumpe
- 1 pm and 8 pm: **How to assign UDI-DI and Basic UDI-DI to my device? Common pitfalls** – Daniel Rubisoier

Thursday, 27 October:

- 9 am and 4 pm: **IVDR state of play with a specific focus on companion diagnostics (CDx)** – Marta Carnielli & James Hewitt
- 10 am and 5 pm: **Challenges with the conformity assessment of Class D devices** – Dr Laura Scrivano, Melanie Ermlich & Dr. Stefan Scheib (Roche Diagnostics GmbH)
- 11 am and 6 pm: **Software- and cybersecurity-specific IVDR requirements: Challenges for regulatory compliance and testing approaches** – Dr Alexander Stock
- 12 noon and 7 pm: **Artificial intelligence – one more challenge for IVDR compliance** – Dr Alexander Stock, Dr Ken Fuh & Dr Catharina Bertram (Johner Institut)
- 1 pm and 8 pm: **Get a head start on TD assessment under In Vitro Diagnostic Devices Regulation (IVDR)** – Dr Ines Labugger

Further information and registration for the Digital Dialogues at: www.tuvsud.com/en/events/digital-dialogues

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

If you are interested in one or more of the specialist topics in our programme, you can make an appointment for (more in-depth) one-to-one talks with our experts.

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