

So that the router does not become a risk: Securely networking medical technology with a new VDE concept

- **Real-time monitoring or the wireless operating theatre bring many benefits for specialist staff and patients through digitalization and networking**
- **In the development of the non-medical devices required for this, lower requirements often apply than for medical technology, which leads to risks for the overall system**
- **With the new VDE concept MD Comp, manufacturers can develop compliant products that can be easily and securely networked – a market with great potential**

(Frankfurt a. M., 26.06.2024) The market for medical technology is growing and is expected to reach a volume of over 500 billion US dollars worldwide in 2024. As digitalization continues to increase in parallel, the demand for non-medical products needed to connect devices in hospitals or doctors' surgeries is rising. The problem is that different security requirements apply to non-medical devices such as routers than to medical devices. This results in risks that become all the more significant with increasing networking. Dipl.-Ing. Hans C. Wenner, Senior Manager Regulatory Affairs at VDE, explains: "It's about electrical safety when products are operated close to patients, or about the ingress of liquids, because products in the operating theater must be resistant to moisture. As far as electromagnetic compatibility is concerned, limit values must be adhered to, as EEG or neuromonitoring systems are very sensitive. Last but not least, cybersecurity plays a major role, as we have to protect patient data." With MD Comp, the VDE has developed a concept that makes it easier for manufacturers to develop compliant products.

Success through reduction: MD Comp focuses on the core requirements

Components that do not have a medical purpose cannot and do not have to meet all the requirements of the European Medical Device Regulation (MDR) and the associated standards. The VDE therefore proposes identifying those technical properties of non-medical devices that

are necessary for compliant and safe integration into medical systems. The first step is to focus on selected chapters of the medical technology safety standard IEC 60601-1.

"It is important that manufacturers consider MD Comp as early as possible in the development process," says Wenner. "Thanks to the structured approach, they can then bring products to market that enable secure networking in the healthcare sector." MD Comp is also a practical aid for start-ups that are developing a medical device for the first time and are overwhelmed by researching standards, for example.

Next steps: developing the first product, sharpening the definition of accessories

As part of the *6G Health* project of the Federal Ministry of Education and Research (BMBF), the VDE is working with partners to apply the MD Comp concept to the development of a non-medical product by the end of 2024. The aim is to extend the approach to other medical technology safety standards. "We are also proposing to link MD Comp with the European legal framework. Our aim is to ensure that certain products are not classified as accessories within the meaning of the MDR, but as a separate category. This will avoid ambiguities in the conformity assessment process," says Wenner.

Information event on MD Comp on July 10

The online information event *MD Comp: How the safe and compliant integration of medical devices and non-medical devices succeeds* will take place on July 10, 2024 from 12 noon to 1 pm. The authors Dipl.-Ing. Hans Wenner (VDE e.V.), Dipl.-Ing. Christoph Lipps (DFKI, Kaiserslautern), Dr. Matthias Flieger (cetecom advanced, Saarbrücken) and Prof. Dr. Boris Handorn (Produktkanzlei, Augsburg) will present the central points of the concept. All interested parties are cordially invited to attend. More information and the registration link can be found [here](#).

About the VDE Recommendation MD Comp

The VDE Recommendation MD Comp – *A practical framework to integrate non-medical devices and medical devices in a compliant way* was developed as part of the *Connected Health* initiative of the 6G Platform Germany and the *6G Health* project under the coordination of the VDE DGBMT Regulatory Affairs Technical Committee. It can be downloaded [here](#) free of charge.

About the German Society for Biomedical Engineering within VDE (VDE DGBMT)

The German Society for Biomedical Engineering in the VDE (VDE DGBMT) is the scientific and technical society for medical technology in Germany. It was founded in Frankfurt am Main in 1961.

The DGBMT in the VDE brings together experts from all areas of technology applications in medicine and deals with the entire range of topics in biomedical technology. It organizes conferences and workshops for expert audiences and is the sponsor of two international scientific journals: Biomedical Engineering and Current Directions in Biomedical Engineering published by Walter de Gruyter. Position papers, statements and expert contributions discuss current topics independently and neutrally. In addition, the DGBMT awards promotional prizes for young scientists, for scientific excellence and innovation, and for patient safety in biomedical engineering. Last but not least, it represents German biomedical engineering in international bodies.

For more information, visit www.vde.com/dgbmt

About VDE:

VDE, one of the largest technology organizations in Europe, has been regarded as a synonym for innovation and technological progress for more than 130 years. VDE is the only organization in the world that combines science, standardization, testing, certification, and application consulting under one umbrella. The VDE mark has been synonymous with the highest safety standards and consumer protection for more than 100 years.

Our passion is the advancement of technology, the next generation of engineers and technologists, and lifelong learning and career development “on the job”. Within the VDE network more than 2,000 employees at over 60 locations worldwide, more than 100,000 honorary experts, and around 1,500 companies are dedicated to ensuring a future worth living: networked, digital, electrical. Shaping the e-dialistic future.

The VDE (VDE Association for Electrical, Electronic & Information Technologies) is headquartered in Frankfurt am Main. For more information, visit www.vde.com

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