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New VDE position paper illustrates how to avoid the impending medical technology chaos

- **The new Medical Device Regulation places significantly higher documentation requirements on manufacturers**
- **VDE provides 32 action recommendations**
- **Position paper calls for rolling reviews and remote audits**

(Frankfurt, June 30, 2022) The European Medical Device Regulation (MDR) has been in force since May 26, 2021. It regulates how medical devices, from ventilators to syringes and implants, can be launched on the market in the European Union. However, a year of seeing the regulation in practice has revealed that it is far too complicated, especially for manufacturers. As a result, hospitals are warning of shortages in the supply of vital medical devices. To address this situation, VDE presented its position paper "European Medical Device Regulation (MDR): Recommendations for implementing the requirements" (in German) today at a virtual press conference. The paper specifically identifies the problems faced by those implementing the MDR and makes recommendations for improving the regulation.

MDR pulls many medical devices off the market

In total, VDE experts examined 17 sub-topics of MDR implementation and drew up 32 action recommendations directed not only at the European Commission but also at the national competent authorities and funding bodies in the field of medical technology. This is evidence itself that the requirements placed on medical devices under the new MDR have greatly increased and lack clarity in many areas. Documentation requirements have multiplied to such an extent that companies are forced to significantly expand their staffing. There are already around 100 guides explaining the incomprehensible and sometimes erroneous text, and the different language versions of the MDR still contain translation errors. "This particularly affects young, small and medium-sized manufacturers of medical devices who have limited resources. Startups and newcomers are also struggling. As a result, the MDR will in all likelihood lead to

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many medical devices and companies being unable to survive on the market," says Christian Otto Erbe, CEO of Erbe Elektromedizin GmbH and Deputy Chairman of the German Society for Biomedical Engineering in VDE (VDE DGBMT).

Time to rethink certification

The certification process is also a major problem. This is the responsibility of the Notified Bodies, meaning private-sector testing organizations that have been nationally accredited in accordance with the new regulation. The MDR has also increased requirements here, and the accreditation process takes longer. As a result, the number of Notified Bodies is still far lower than the number accredited under the old Medical Device Directive. Dr. Cord Schlötelburg, Director of VDE Health, points out that many manufacturers currently have a hard time finding a Notified Body with spare capacity: "It would be useful to introduce an EU service center for spare capacity. We also run the risk of a huge capacity bottleneck caused by existing products seeking recertification before the end of the MDR transition period on May 26, 2024. VDE recommends that the bodies conduct rolling reviews, meaning step-by-step certification. It should also be possible to carry out remote audits on a larger scale."

In addition, the VDE paper calls on the European Commission to find a realistic way of dealing with the documentation requirements, especially in the clinical evaluation of existing products whose Notified Body certificate will expire on May 26, 2024, at the latest. VDE suggests extending the transition period for companies to deliver clinical data as part of the Post-Market Clinical Follow-Up (PMCF). A Notified Body could then issue an MDR compliance certificate provisionally as part of a rolling review stipulating that this documentation be submitted later.

EUDAMED remains incomplete

For Prof. Jens Haueisen, head of the Institute of Biomedical Engineering and Informatics at the Technical University of Ilmenau and Board Chairman of VDE DGBMT, there is also no clear reason why Europe's EUDAMED database for medical devices is still not fully operational despite being a central element of the new MDR. EUDAMED is intended to be the central point for information on medical devices launched on the market. As such, it also serves as a basis for extensive registration obligations. The EU has not yet delivered here – only three of the six database modules are currently (partially) available. Moreover, the technical design of EUDAMED is outdated and insufficiently user-friendly. VDE is therefore calling for the European medical device database to be made fully operational as soon as possible.

Manufacturers of AI-based medical devices still feel left behind, as they are likely to face even more EU legislation (the proposed Artificial Intelligence Act (AIA) and Artificial Intelligence Liability Act (AILA) and will therefore be subject to double the requirements. VDE believes it is

worth considering whether medical devices should be exempted from additional legislation in this area.

“If the European Commission does not act quickly, many medical technologies made in Europe will no longer be on the market – with disastrous side effects for patients,” Haueisen fears. VDE therefore recommends comprehensively assessing the real impact of the MDR on patient care. Regulation is important, but it should not prevent patients from benefiting from new medical devices.

The VDE position paper “European Medical Device Regulation (MDR): Recommendations for implementing the requirements” is available free of charge (in German) at https://www.vde.com/de/dgbmt/arbeitsgebiete/fachausschuesse/fa-regulatory-affairs

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

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

VDE DGBMT networks experts from all areas of technology applications in biology and medicine. With approximately 2,000 members and 23 expert committees, it covers the entire range of topics in biomedical engineering. In addition, it offers conferences and workshops for specialist audiences and is the sponsor of two international scientific journals: Biomedical Engineering and Current Directions in Biomedical Engineering published by Walter de Gruyter. The DGBMT also awards prizes for young scientists, for scientific excellence and innovation, and for patient safety in biomedical engineering. Last but not least, it represents German biomedical technologies in international committees.

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 125 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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