PRESS

2023/024
17.05.2023

VDE at MedtecLIVE with T4M 2023: Spotlight on medical software approval

- **MDR is a key issue again this year**
- **VDE event on concrete implementation of current regulatory requirements for software as a medical device**
- **Documentation effort inhibits development of innovations for patients**

(Frankfurt a. M./Nuremberg, 17.05.2023) The European Medical Device Regulation (MDR) has been in effect for manufacturers for about two years now. The challenges are immense. Therefore, the EU Commission has again significantly extended the transition periods. This means that certificates that have already been issued are valid for longer. However, to a large extent, the problem is only being pushed back. The fact is that regulatory requirements in Europe have risen sharply. MDR will therefore also be an important topic at MedtecLIVE with T4M 2023. At the European trade fair for medical technology, product developers and buyers from distributors, OEMs and suppliers will exchange views on the current challenges in the industry from May 23-25 in Nuremberg.

Regulation prevents innovations

At MedtecLIVE with T4M, VDE will be addressing the approval of software as a medical device. Artificial intelligence, for example, has the potential to revolutionize the medical field as well. With the unsatisfactory legal situation in Europe, companies could be left behind compared to their competitors from the USA, for example, says Dr. Cord Schlötelburg, Head of VDE Health: "With the MDR, Europe has created a regulation that hinders innovation. We want to show smaller and medium-sized companies in particular how they can still remain competitive in medical technology."

VDE Verband der Elektrotechnik Elektronik Informationstechnik e. V.
V.i.S.d.P. Head of Brand, Marketing and Communication: Thomas M. Koller
Merianstraße 28
63069 Offenbach am Main
www.vde.com
presse@vde.com

Entire processes and documentation must be MDR-compliant

For both existing and new products, the entire processes and documentation must be revised or newly created and thus made compliant with the Medical Devices Ordinance. This requires corresponding investments in know-how, infrastructure and employees and is a challenge especially for small and medium-sized companies, such as start-ups or innovative high-tech SMEs. During MedtecLIVE, VDE will therefore discuss with its experts how medical software can reach the market safely, quickly and compliantly.

Regulation of medical software at MedtecLIVE with T4M

Dr. Cord Schlötelburg and Dr. Thorsten Prinz, Senior Manager VDE, will discuss the impact of MDR on the approval of medical software together with industry lawyer Dr. Zeynep Schreitmüller from the product law firm and Peter Hartung from the consulting company seleon GmbH. Among other topics, they will discuss the certification of AI products and what start-ups should consider.
Event details: Messezentrum, Messepiazza 1, Nürnberg Messe, May 23, 2023, 13:00 – 14:15

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

Press contact: Vanessa Rothe, Phone +49 170 7645316, presse@vde.com