PRESS

2023/040
28.08.2023

VDE DGBMT calls for market access for continuous learning AI systems in medicine

- **Impeding innovation: Continuous learning AI systems are currently not allowed to be marketed as medical devices in the EU**
- **German Society for Biomedical Engineering in the VDE (VDE DGBMT) makes proposals for a new regulatory framework**
- **Recommendation is primarily aimed at authorities, notified bodies and European legislator - free webinar on 21.09.2023**

(Frankfurt a. M., Aug. 28, 2023) Artificial intelligence systems offer promising applications in medicine. They can assist in the diagnosis of diseases as the evaluation of image data, for example in CT or MRI scans. They can even help with treatment, for example by using AI to analyze patient data or to predict how well a therapy will work. Accordingly, more and more AI systems have been approved as medical devices in Europe or the US in recent years. However, these are usually so-called static AI systems: The learning process must be completed before the system is put into operation, and the underlying AI model may no longer change.

In contrast, continuous-learning AI systems do not have a fixed technical development status. They continue to be trained with new data during the market phase to improve the performance of the AI model. Having said that, they are currently not allowed to be placed on the European Union market and marketed as medical devices for medical applications.

Taking into account future European Artificial Intelligence Act (AIA)

The German Society for Biomedical Engineering within the VDE (DGBMT) has therefore drawn up proposals as to what an alternative to the current innovation-inhibiting approach might look like. The DGBMT experts have analyzed the current European regulatory framework for medical devices and compared it with existing proposals for a new regulatory framework. The future European Artificial Intelligence Act (AIA) has also been incorporated into the VDE DGBMT

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

recommendation: The core element is a so-called "anticipatory CE conformity assessment", which provides for the planning and approval of intended changes even before the device is put into operation.

Anticipatory CE conformity assessment

Before placing their products on the market, manufacturers of medical devices must demonstrate the conformity of their products with the requirements of the Medical Device Regulation (MDR), or In Vitro Diagnostic Regulation (IVDR). After completion of the conformity assessment procedure, manufacturers issue an EU declaration of conformity and affix the corresponding CE marking to the product.

An anticipatory CE conformity assessment would be characterized by the fact that it is carried out in advance, including the intended changes in the course of commissioning. For subsequent changes that are within the scope of what has been approved, further approval by the notified bodies could be dispensed with. Changes that cannot be foreseen and cannot necessarily be anticipated would then have to be subjected to a new conformity assessment procedure and subsequently certified.

Free online event on 21.09.2023

The entire recommendation **"Market Access of Continuous Learning AI Systems in Medicine"** is available for download (German version) on the DGBMT website. On Thursday, Sept. 21, 2023 from 10 to 11 a.m., DGBMT experts will present the main contents of the recommendation in a free online event (in German) and will be available to answer questions. You can register here.

Interested journalists are also cordially invited.

About DGBMT in VDE

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

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