CONNECT

Artificial intelligence accelerates certification process

Background

The joint project KIMEDS aims to make medical technology software certification more transparent and efficient for the entire medical technology sector. The Federal Ministry of Education and Research has also recognised the potential that the development of the standardised AI-supported system holds for health care and is funding it over 36 months with a sum of 1.46 million euros.

Medical software on the rise

In times of digitalisation, the development of cyber-medical systems and programmable electronic medical systems up to semi-autonomous or robotic assistance systems is increasing strongly. These systems offer medical technology new possibilities due to their precision and at the same time gentler diagnostic or therapeutic procedures and have the potential to revolutionise the healthcare system. However, like all other medical devices, these systems also face the challenge of being approved. This process is not only lengthy, but also strictly regulated in terms of documentation. The KIMEDS project, whose consortium consists of several companies, authorities, medical professionals and German research institutions, is pursuing the goal of guiding new, innovative medical devices and their control software through the approval and certification process more quickly and transparently by using artificial intelligence and thus making them accessible for clinical practice.

With the help of AI, a standardised system is to be developed that will help optimise and accelerate the approval of software-based medical technology. In doing so, an integrated, AI-based approach to monitoring product safety risks will be promoted, which will safeguard the complete life cycle of medical software from development to product certification and product monitoring.

Compared to conventional medical devices, software-based medical devices are both more complex and more networked and agile, which is why the formal proof of safety required for certification is also more complex and thus more time-consuming. Often, the parties involved are slowed down by tables and/or text documents for risk assessment and safety documentation that have to be prepared manually. In addition, individual product development processes are not electronically coordinated, which in turn leads to delays. With the AI-based system of KIMEDS, safety records should be created faster and more transparently in the future, which will have a positive effect on patient safety on the one hand and on the retrospective observation of incidents on the other.

The familiarisation with extensive certification documentation and associated documents in clinical trials or risk notifications makes it difficult for regulatory authorities to efficiently assess risks, which has a negative impact on the implementation of corrective measures to ensure patient safety. The new KIMEDS system also aims to address this problem by asking for specific safety aspects in the risk documentation. In this way, new problems and their specific causes can be narrowed down more quickly and manufacturers can also initiate corrective measures more quickly.

In order to achieve the acceleration of medical technology software certification within the entire industry, work is being carried out on the development of a pilot solution that is to form the basis for international standardisation. With the help of special AI software tools, it should be possible to check complex and difficult-to-understand specifications for their completeness, consistency and logic. The aim of the project is thus to achieve a holistic improvement in the safety, transparency and certification of programmable electronic medical systems. The establishment of an internationally compatible and standardised, modern AI-supported regulatory system of interoperable software tools could map the complete life cycle in the future. The advantage is that the preparation of safety documentation starts directly in the software development process and is supported by a permanent validity check by the AI system. In addition, the system helps to prepare the evaluation of a structured proof for certification, which results in a considerable gain in efficiency.

Would you like to learn more about the KIMEDS project? We have researched the players involved for you. Would you like more information on the topic? arcoro connects innovation ideas, research institutions and companies.

PARTICIPANTS	LOCATION	WEBSITE
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	Germany	https://www.bfarm.de/DE/Home/_node.html
EKFZ Dresden	Germany	https://digitalhealth.tu-dresden.de/
iSAX GmbH & Co. KG	Germany	https://www.isax.com/
TU Dresden - International Center for Computational Logic	Germany	https://iccl.inf.tu-dresden.de/web/International_Center_for_Computational_Logic
Siemens Healthineers AG	Germany	https://www.siemens-healthineers.com/de
TÜV Süd	Germany	https://www.tuvsud.com/
Biotronik SE & Co. KG	Germany	https://www.biotronik.com/
B. Braun SE	Germany	https://www.bbraun.de/de.html
Ovesco Endoscopy AG	Germany	https://ovesco.com/de/
Carl Zeiss AG	Germany	https://www.zeiss.de/corporate/home.html
Secunet Security Networks AG	Germany	https://www.secunet.com/
Johner-Institut GmbH	Germany	https://www.johner-institut.de/
MED-EL Elektromedizinische Geräte Deutschland GmbH	Deutschland	https://www.medel.com/