Press Release

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TÜV SÜD: Intended purpose turns software into a medical device

Munich. Software used for medical intended use is regarded as a medical device under the new regulation, a fact that is overlooked time and again by developers, manufacturers and distributors. In cases of doubt, TÜV SÜD's recommendation is to verify conformity with the MDR and IVDR and follow the MDCG guidance for software qualification and classification.

"Sometimes software manufacturers are unaware that the product they are developing is actually a medical device, and are then unsure about which regulatory requirements they have to fulfil", says Dr Abtin Rad, Global Director Functional Safety, Software and Digitization at TÜV SÜD. "Even a smart watch app that monitors the user's heart rate to make a diagnosis or recommend treatments is a medical device." Another example is software that controls an insulin pump and calculates the correct dosage. A critical role in classification is played by the intended purpose – in other words, whether software is used to predict the course of, diagnose or examine a disease and to recommend or influence treatments.

Apps on prescription and guidance for download

Medical apps have been available on prescription in Germany since October 2020. Digital health applications require assessment and registration by the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte). Among other requirements, manufacturers must furnish evidence that their devices are in conformity with the EU regulations. A precondition of this is CE marking as a medical device in risk class I or IIa. The Medical Device Coordination Group, an international expert committee, provides detailed guidance on software qualification and classification in its publication MDCG 2019-11. The relevant requirements and criteria are set forth in the Medical Device Regulation (MDR 2017/745) and the Regulation on In Vitro Diagnostic Medical Devices (IVDR 2017/746).

As a Notified Body, TÜV SÜD offers testing and certification of software for medical devices in accordance with the relevant software standards. With more than 750 medical device professionals in

30-plus locations worldwide, TÜV SÜD is considered the largest EU Notified Body authorised to provide testing and certification services under the MDR and IVDR.

Further information about TÜV SÜD's seminars can be found at:
https://www.tuvsud.com/en/industries/healthcare-and-medical-devices

MDCG guidance on qualification and classification of software at:
https://ec.europa.eu/docsroom/documents/37581/attachments/1/translations/en/renditions/native

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