Press Release

New TÜV SÜD white paper

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Artificial Intelligence in Medical Devices

Munich. TÜV SÜD has published a new white paper under the title of “Artificial Intelligence in Medical Devices – Verifying and validating AI-based medical devices”. The publication discusses the opportunities and challenges faced by device manufacturers seeking to bring new technologies to market, including medical devices incorporating artificial intelligence, that are safe for both patients and health professionals. The white paper also provides an overview of the essential criteria to be considered by manufacturers when developing and evaluating innovative designs that incorporate these advanced technologies.

The potential application of artificial intelligence (AI) in particular machine learning (ML) holds significant promise for the health sector. By leveraging advanced algorithms and vast amounts of data generated through their routine use, AI-enabled medical devices and software as a medical device (SaMD) can quickly adapt to new information and changing conditions and optimise their performance in real time. These advantages can lead to improved treatment outcomes for patients, resulting in reduced costs and substantial gains in the overall quality of healthcare everywhere.

However, the regulatory requirements in the European Union (EU) and other important medical markets do not currently consider the unique and complex requirements of medical devices that include AI and machine-learning technologies. “AI technologies have the power to transform our world. However, the gap between the advanced technologies available now and the existing regulations poses a myriad of challenges to medical device manufacturers seeking device approval, while potentially putting patients at risk”, warns Dr Abtin Rad, Global Director Functional Safety, Software and Digitization at TÜV SÜD and the author of this white paper.

The growing acceptance of AI-enabled medical devices is only one aspect of this global transformation. However, further development is dependent upon the existence of standards and designations specifically designed to assess the unique performance and safety issues associated with these types of technologies.

Organisations developing medical technologies with embedded AI capabilities should strongly consider a more expansive approach in assessing the safety of their products. This type of approach would address every aspect of the product planning and development process, and extend beyond the initial product release date to include rigorous post-market surveillance activities.

To assist developers and manufacturers in evaluating these processes, the Association of Notified Bodies for Medical Devices in Germany (IG-NB) has issued a comprehensive "Requirements Checklist" for assessing the safety of AI-enabled medical technologies (https://www.ig-nb.de/dok_view?oid=824260, an English version of the document is available on the website of the Johner Institute at www.johner-institute.com). This checklist, compiled with the assistance of TÜV SÜD, is aimed at closing the current compliance gap for manufacturers of AI-controlled medical devices. These efforts can provide an important pathway for those seeking to achieve global compliance, and can facilitate the timely introduction of innovative technologies when we need them the most.

The white paper in English is available as a free download at: https://www.tuvsud.com/en/resource-centre/white-papers/artificial-intelligence-in-medical-devices

Media Relations:

Dirk Moser-Delarami TÜV SÜD AG Corporate Communications Westendstr. 199, 80686 Munich, Germany	Tel. +49 (0) 89 / 57 91 – 15 92 Fax +49 (0) 89 / 57 91 – 22 69 Email dirk.moser-delarami@tuvsud.com Internet www.tuvsud.com