Press Release

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Changes in the EU Medical Devices Regulation 16 February 2023

TÜV SÜD welcomes new transition periods

Munich. On 6 January 2023, the European Commission published a proposal to amend the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) to reduce the risk of shortages. Today, 16 February 2023, the European Parliament has voted positively with overwhelming majority on the draft. As Council agreed already in late January, the amendment is de facto accepted. The Notified Body TÜV SÜD Product Service GmbH welcomes the amendment in the interest of patient safety and continues to call on manufacturers to act promptly.

In principle, manufacturers will now be given more time to bring existing products into compliance with the MDR. Depending on the risk class, the validity of the MDD certificates will be extended until 2027 or 2028. This extension of the deadline brings important relief for the timetables of manufacturers and Notified Bodies.

Overview of the main elements for change

For medical devices with a certificate or declaration of conformity issued before 26 May 2021, the transition period to the new rules will be extended as follows:

- For custom-made implantable devices in class III: until 26 May 2026.
- For higher-risk devices: until 31 December 2027. This includes Class III devices and Class IIb implantable devices, excluding sutures, braces, dental fillings, dental braces, dental crowns, screws, wedges, plates, wires, pins, clips and connectors.
- For medium and lower risk products: until 31 December 2028. This includes other class IIb products, class IIa products and products of classes Is, Im, Ir.

The extension is subject to certain conditions. This means more time will only be granted for products that are safe and for which manufacturers have already taken steps to convert to MDR: The application must be submitted by 26 May 2024 at the latest and the contractual agreement with the Notified Bodies must be concluded by 26 September 2024 at the latest.

The sell-off period for existing products previously specified in the Medical Devices Regulation (MDR Art.120(4)) and In Vitro Diagnostic Medical Device Regulation (IVDR) Art 110(4) has also been abolished to allow medical devices already placed on the market to be made available beyond the end date of May 2025.

The next official step for the amendment of the MDR/IVDR is the signing and subsequent publication in the Official Journal. On that day, the draft regulation will then enter into force.

Manufacturers must take action now – even with the new deadlines

“TÜV SÜD expressly welcomes the adoption of the amendment. The new deadlines will ensure that patients and healthcare professionals will continue to have safe medical devices. In addition, we are involved in all necessary activities with EU authorities and other stakeholders to ensure the successful implementation of the regulation,” says Dr Royth von Hahn, Global Senior Vice President Medical & Health Services at TÜV SÜD.

The procedure of the new EU Medical Devices Regulation is known to be complex and sometimes requires longer processing times. At the same time, the number of notified bodies assessing conformity is still manageable. TÜV SÜD has, at an early stage and steadily, built up capacities and is in constant close exchange with manufacturers on the changeover. However, they must also become active now in the new situation and work at full speed on the planning.

TÜV SÜD has its own website with useful information for manufacturers. To prepare the technical documentation, the associated "Guidance for Submitting Technical Documentation to TÜV SÜD" on the TÜV SÜD website is helpful. In active customer communication, holders of MDD and AIMDD certificates issued by TÜV SÜD Product Service GmbH are informed and advised to submit a qualified application promptly, even with the new deadlines. Timely processing cannot be guaranteed if the assessment dates are planned (too) late, nor can the seamless transition to MDR certificates.

TÜV SÜD has always taken its responsibility in the supply of safe, effective and also established medical devices very seriously and is therefore also prepared now. “We know that all market participants are united by the ambition to strengthen the future viability of Europe as a medical device location through innovative products and a high-performance approval system,” says Royth von Hahn, describing the current situation.

More than 1,200 medical device experts at over 30 locations

TÜV SÜD is one of the first Notified Bodies worldwide to be approved for MDR testing. Medical & Health Services has also steadily built capacity over the past four to five years (CAGR of almost 20 %) and is now present with more than 1,200 medical device experts at over 30 locations worldwide.

Further informationen: https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation/info-on-mdr-transition and https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation

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