TÜV SÜD Danmark ApS designated as a notified body for medical devices in Denmark

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Medical devices to be placed on the EU market must be assessed by a notified body to verify whether the device and manufacturer comply with EU medical devices legislation. If the device and manufacturer are certified, they will get a CE mark, which shows that the device is safe, effective, and can be placed on the market.

The EU Medical Devices Regulation from 2021 tightened the requirements and necessitated specialized expertise in EU notified bodies. This is due to technological developments and patient safety. As a result, several notified bodies have been closed, while new notified bodies must go through an extensive designation process.

The Danish Medicines Agency was responsible for designating the appropriate Danish notified body. The Agency will continue to supervise the notified body in the future. The selection was made in collaboration with the Danish Ministry of the Interior and Health, the Danish Ministry of Industry, Business and Financial Affairs, the EU Medical Device Coordination Group, and the European Commission. The contract has been underway since 2020 when the Danish Ministry of Trade and Industry awarded TÜV SÜD Danmark ApS, an entity within the TÜV SÜD Group, the contract following tender proceedings. TÜV SÜD Danmark ApS is tasked with certifying 39 devices codes under the Medical Devices Regulation.

This is the first time in many years that a notified body for medical devices is domiciled in Denmark. Previously, Danish companies had to obtain their designation from foreign notified bodies with long processing times. This

whole application process has been complex and extensive, which delayed the designation. This was because it took a long time to review, assess and verify whether TÜV SÜD Danmark ApS had the necessary competencies and met the requirements for notified bodies under the EU Medical Devices Regulation.

TÜV SÜD Danmark ApS began performing its services on April 6, 2024.

Click here to read the news release published (in Danish) by the Danish Medicines Agency

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