

Press release

Gothenburg, Sweden, on March 1, 2024

TÜV SÜD is temporarily suspending Getinge's CE certificate for Cardiosave

The notified body, TÜV SÜD, is temporarily suspending the CE certificate for Getinge's Cardiosave Intra-Aortic Balloon Pump with immediate effect. Getinge is given six months to adhere to the required corrective actions. The financial impact is not expected to be material for Getinge.

As previously communicated by Getinge, the CE certificate for Getinge's subsidiary Datascope Corp. for the Cardiosave Intra-Aortic Balloon Pump, was reinstated by TÜV SÜD in July 2023 after approximately three months of suspension due to gaps identified in compliance with applicable regulation. This decision was complemented with conditions to be fulfilled to maintain the CE certificate. The certificate is mandatory for deliveries of Cardiosave in countries requiring CE certification.

TÜV SÜD has now evaluated the compliance with the conditions for Getinge and assessed that they are only partially fulfilled. Specifically, the notified body requests Getinge to accelerate implementation of committed product improvements and ongoing field safety corrective actions for Cardiosave. Component shortages, as Getinge has communicated about earlier, is one of the reasons for not meeting timeline to implement improvements.

Consequently, TÜV SÜD has decided to immediately suspend the CE certificate for six months. During the suspension, Getinge will not be able to provide intra-aortic balloon pumps to customers requiring the CE certificate, which represents approximately 100 MSEK of the annual sales of Cardiosave.

TÜV SÜD's decision does not affect the installed base of Cardiosave. This means, products already on the market can continue to be used and devices already in distribution can be delivered. Intra-Aortic Balloon catheters and spare parts are not affected by this decision.

"We are aware of the very problematic situation this suspension puts on healthcare providers and critically ill patients. Therefore, in close dialogue with TÜV SÜD, we are working urgently to minimize the impact. All affected customers will receive continuous information from us," says Elin Frostehav President Acute Care Therapies at Getinge.

In parallel with the efforts to regain the CE certificate for Cardiosave, Getinge is accelerating development of the next product generation.

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About Getinge

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions that aim to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.