

Press release

Gothenburg, Sweden on March 27, 2023

TÜV SÜD suspends CE-certificate for Getinge's Cardiosave

The notified body for certification services, TÜV SÜD, has decided to suspend the CE-certificate for Getinge's Intra-Aortic Balloon pump Cardiosave, effective immediately. The company has been given three months to adhere to the required corrective actions.

The notified body, TÜV SÜD, has issued an immediate suspension of the CE certificate for intra-aortic balloon pumps for up to three months. The suspension is based on concerns related to risk management, post market surveillance and vigilance, as well as information pertaining to timeliness of field safety corrective actions.

During the three months, Getinge will not be able to provide balloon-pumps to customers requiring CE certificate, which represents SEK 70 M of the annual sales of Cardiosave Intra-Aortic Balloon pumps. Pumps already on the market can continue to be used and devices already in distribution can be delivered. Balloons and spare parts are not affected.

Getinge is aware of the severe situation this suspension puts on healthcare providers and critically ill patients. The company is in dialogue with TÜV SÜD and working urgently to minimize the impact on patients. All affected customers will receive communication from Getinge.

Given the information Getinge has today, the financial impact is not expected to be material.

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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.