Press release

Gothenburg, Sweden, on August 4, 2025

EU CE-Mark Reinstated for Cardiosave Intra-Aortic Balloon Pump

Today, Getinge announces that the EU Notified Body TÜV SÜD has reinstated the EU CE Mark for Getinge's Cardiosave Intra-Aortic Balloon Pump (through the issuance of an updated EU Medical Device Directive (MDD) Confirmation Letter).

The MDD Confirmation Letter for Getinge's Cardiosave Intra-Aortic Balloon Pump was temporarily suspended by TÜV SÜD in March 2024 for an initial six months, a period that was later expanded until July 1, 2025. A Confirmation Letter is issued by EU Notified Bodies to Companies to confirm and allow for the transition from the EU MDD to the EU Medical Device Regulation (MDR).

The Cardiosave IABP CE-mark was suspended due to gaps in compliance to the applicable Medical Device Directive. Specifically, TÜV SÜD requested Getinge to accelerate implementation of product improvements to address open field safety corrective actions. Getinge developed and has now received TÜV SÜD approval for multiple design improvements. These improvements will be implemented into production and into the Getinge service program for installed devices in the markets that accept the CE-mark. The same design improvements will be also made available to other markets upon approval by the respective Health Authority.

"We are aware of the challenges the CE-mark suspension has caused for healthcare professionals and patients. Our teams have worked persistently to adhere to the required corrective actions in close dialogue with our Notified Body, TÜV SÜD." says Elin Frostehav, President Acute Care Therapies at Getinge. "Ensuring that healthcare professionals and patients have access to our life-saving devices remains our number one priority and we are pleased to achieve CE-mark reinstatement which enables us to again provide this device to customers in countries accepting the EU CE-mark to help improve cardiac outcomes."

The reinstatement is subject to certain conditions, which Getinge is committed to fulfilling. Deliveries of Cardiosave IABP to CE markets are expected to resume in Q4 2025.

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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 aiming 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 approximately 12,000 people worldwide and the products are sold in more than 135 countries.

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