Press release

Gothenburg, Sweden on September 25, 2024

Getinge’s CE certificate for ECLS consumables reinstated

The notified body, TÜV SÜD, reinstates Getinge’s CE certificate for HLS and PLS consumables, used for ECLS therapy, with certain conditions. Temporary challenges with a supplier and production changeover related to the new packaging solution have resulted in a lower volume of HLS and PLS sets available for shipment in Q3 2024, which is expected to be phased into Q4 2024.

In March 2023, Getinge’s CE certificate for the consumables HLS and PLS sets used for extracorporeal life support (ECLS) was suspended due to a potential defect in the sterile packaging. However, under the exemption provided by EU MDR Article 59, sales have still been able to continue to countries that require CE certification.

As previously communicated by Getinge, a new packaging solution has been developed, and an application for CE approval was submitted to the notified body TÜV SÜD in Q2 2024. TÜV SÜD has now evaluated Getinge’s application and decided to reinstate the CE certificate, with certain conditions to be fulfilled. Getinge expects to regain deliveries of mentioned products in Q4 2024.

The reinstatement of the CE certificate is a result of committed work and a close and constructive dialogue between Getinge and TÜV SÜD. However, quality problems with deliveries from a key supplier and production changeover related to the new packaging solution, have resulted in a lower volume of HLS and PLS sets available for shipment in Q3 2024, which is expected to be phased into Q4 2024.

“We are aware of the very problematic situation this product shortage puts healthcare professionals and critically ill patients in. Therefore, we are working urgently and in close dialogue with our customers to minimize the impact,” says Elin Frostehav, President Acute Care Therapies at Getinge.

TÜV SÜD has also announced that the temporary suspension of Getinge’s Cardiosave Intra-Aortic Balloon Pump, effective from March 2024, will be extended until July 1, 2025. This decision does not affect the already installed base of Cardiosave. This means that products already on the market can continue to be used. Consumables, service, and spare parts for the pumps are not affected. The decision is not deemed to be financially material for Getinge.

Getinge AB (publ)
P.O. Box 8861
402 72 Gothenburg
Sweden

Phone: +46 (0)10 335 00 00
Email: media@getinge.com

www.getinge.com

Contact information:

Lars Mattsson, SVP Corporate Development (Corporate Strategy, M&A and IR)
Phone: +46 (0)10 335 0043
Email: lars.mattsson@getinge.com

David Kördel, Head of Investor Relations
Phone: +46 (0)10 335 0077
Email: david.kordel@getinge.com

Caroline Örmgård, Head of Public & Media Relations
Phone: +46 (0)10 335 0041
Email: caroline.ormgard@getinge.com

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