

## Press release

Gothenburg, Sweden on February 23, 2023

### **DEKRA temporarily suspends certificates for Getinge's HLS and PLS sets**

**The notified body for certification services, DEKRA, has decided to temporarily suspend the CE-certificates for Getinge's HLS and PLS sets from March 1, 2023. Getinge is in dialogue with authorities and working urgently to minimize the impact on patients.**

As previously communicated, Getinge has identified and announced potential breaches in sterile packaging of the HLS and PLS sets used for extracorporeal respiratory and/or cardiovascular support. Getinge has since then reported progress to relevant authorities on a number of initiatives, such as package design improvements and advanced testing of the packaging to ensure that the products are protected by a sterile barrier according to the applicable standards and requirements.

According to DEKRA the documentation related to the initiatives submitted from Getinge does currently not demonstrate compliance with the essential requirements according to the Medical Device Directive and applicable standards. As a result, DEKRA will temporarily suspend the certificates for the HLS and PLS sets from March 1, 2023.

Getinge is aware of the severe situation this suspension puts on healthcare and critically ill patients. The company is in dialogue with authorities and working urgently to minimize the impact on patients. The extensive work is continuing to secure compliance with essential requirements. All affected customers will receive communication from Getinge.

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

#### **Investor Relations:**

Lars Mattsson, Head of Investor Relations

Phone: +46 (0)10 335 0043

Email: [lars.mattsson@getinge.com](mailto:lars.mattsson@getinge.com)

#### **Media contact:**

Anna Appelqvist, Vice President Corporate Communications

Phone: +46 (0)10 335 5906

Email: [anna.appelqvist@getinge.com](mailto:anna.appelqvist@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 over 10,000 people worldwide and the products are sold in more than 135 countries.