

## DEKRA temporarily suspends certificates for HLS and PLS sets

Dear valued customer,

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.

Getinge has now been informed by the notified body for certification services, DEKRA, that the documentation related to the initiatives submitted from Getinge currently does 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 ship hold will be effective as from February 28, 2023, end of day. Please accept our sincere apologies.

Getinge is in contact with authorities and working urgently to minimize the impact on patients. We will keep you informed about the situation.

Yours sincerely,



Avril Forde

President Northern Europe Region