Press release

Gothenburg, Sweden, on December 4, 2019

Getinge is announcing a voluntary recall of the ROTAFLOW drive unit

Getinge is announcing a voluntary global medical device recall of the ROTAFLOW drive unit. To date, there are no known adverse events associated with illness or injuries related to the drive unit. Getinge has reported to relevant authorities according to applicable regulations and the cost for the field correction and recall is not material.

The ROTAFLOW Centrifugal Pump System is a device that is indicated as a component of the extracorporeal circuit for pumping blood. Getinge is initiating a voluntary Medical Device Recall for the ROTAFLOW Drive Unit due to a loose coaxial cable connection that may result in fluctuating flow values on the ROTAFLOW Console.

All concerned customers have received communication from Getinge. The product will be corrected and returned to customers.

This information is released in order to inform users of mentioned Getinge products, according to standard procedures recommended by regulatory authorities.

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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.