

Press release

June 3, 2019
Gothenburg, Sweden

Getinge informs about a medical device recall for Custom Tubing kits for Heart Lung Machine

Getinge is informing about a medical device recall for the custom tubing kits for Heart Lung Machines. To date, there are no known adverse events associated with illness or injuries for the products. Getinge has reported to relevant authorities according to applicable regulations and the cost for the field correction and recall is not material.

The Heart Lung Machine (HLM) Tubing Set is part of an extracorporeal system and is used exclusively in combination with other devices of that system, e.g. blood pumps, oxygenators etc. The HLM Tubing Sets are designed to be used for circulation of blood and other liquids between the patient and the extracorporeal system. This recall is initiated due to an identified issue with the cap on a stopcock, which can restrict airflow into the downstream port. This restriction of flow into the port creates an increased challenge to the sterilization process for the stopcock included in the kit.

All concerned customers have received communication. Customers are requested to return any remaining HLM Tubing Sets for replacement or full credit.

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

Media contact:

Anna Appelqvist, Vice President Corporate Communications
Phone: +46 (0)10 335 5906
E-mail: 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.