

Press release

Gothenburg, Sweden on November 21, 2022

U.S. Food and Drug Administration broadens the consent decree with Getinge and includes its subsidiary Datascope

U.S. Food & Drug Administration (FDA) will include Getinge's subsidiary Datascope as an additional facility in the company's existing consent decree with the U.S Government. This is due to findings from previous FDA inspections and a warning letter related to operational compliance with the company's quality management system and processes.

Getinge has today responded to FDA and accepted that Datascope will be included in the existing Consent Decree. FDA's conclusion relates to a previously communicated warning letter in 2019 and subsequent inspections at the Datascope site in Wayne, NJ, US, between November 1, 2021 and January 21, 2022. According to FDA, Getinge's subsidiary Datascope has failed to fully comply with the Quality Management System and related processes.

Datascope is enforcing the ongoing actions to address the findings from the inspections and warning letter and to ensure that the organization act in compliance with the Quality Management System. The company is implementing a new operational quality organization with new leadership closer and integrated in the business operations. A work plan for further improvements for the site will be submitted to FDA in January 2023, in accordance with standard procedure and an independent auditor will be appointed.

Datascope's improvement activities 2018-2022 amount to approx. SEK 500 M from 2018. The additional costs for the improvements going forward are not expected to be material.

Datascope is a subsidiary of Getinge, and manufacturer of life-supporting medical devices such as Intra-Aortic Balloon Pumps. Datascope's products are sold globally and will continue to be available for customers.

Phone Conference

A conference call will be held on November 21, 2022, at 5.00 p.m. (17:00) CET hosted by Mattias Perjos, President & CEO. Please see dial in details below to join the conference:

Sweden: +46 856642651

United Kingdom: +44 3333000804

United States: +1 6319131422

PIN: 12992271#

During the conference call a presentation will be held. To access the presentation through webcast, please use this link: <https://tv.streamfabriken.com/press-conference-november-2022>

Alternatively, use the following link to download the presentation:
<https://www.getinge.com/int/company/investors/reports-presentations/>

Media contact:

Lars Mattsson, Head of Investor Relations

Phone: +46 (0)10 335 0043

Email: lars.mattsson@getinge.com

Anna Appelqvist, Vice President Corporate Communications

Phone: +46 (0)10 335 5906

Email: anna.appelqvist@getinge.com

This information is such that Getinge AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on November 21, 2022, at 16.10 CET.

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.