

Press Release

July 17, 2017
Gothenburg, Sverige

Getinge has replanned the remediation in Hechingen (DE) related to the Consent Decree with FDA and makes a provision of additional SEK 488 M

As previously communicated the remediation program has continued at the Getinge production sites under the Consent Decree with FDA. A replanning of the ongoing remediation program has been conducted in Hechingen, Germany, and the Group has decided to make an additional provision of SEK 488 M to make the necessary changes.

The costs are primarily attributable to increased staffing and process validation. After the decided provision the Group has a total remaining provision of SEK 710 M.

As previously announced a US federal judge approved the terms of a Consent Decree between Getinge's former Medical Systems business area (corresponding to Acute Care Therapies today) and the FDA on February 3, 2015. The Consent Decree establishes a framework that provides assurances to the FDA that Getinge will complete the improvements to strengthen the quality management system. The Consent Decree originally encompasses four legal entities: Atrium Medical Corporation in Hudson (New Hampshire, USA), Wayne (New Jersey, USA), Rastatt (Germany) and Hechingen (Germany).

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This information is information 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, at 08:00 CEST on July 17, 2017.

About Getinge

Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the everyday life for people - today and tomorrow.