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# Medical Systems

# **FDA - Consent Decree**

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Johan Malmquist, CEO

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## Background

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- In 2013, FDA inspected 10 of Medical Systems manufacturing facilities, which generated observations related to the quality management system.
- As previously disclosed, Getinge has committed substantial investments, SEK 995 million, into the remediation work to strengthen the quality management system. The total remediation cost has been recognized during 2014.
- The remediation work has already led to significant improvements and the goal is to conclude the remediation program by the middle of 2016.
- In parallel with the remediation work, Medical Systems has been in dialogue with the FDA.

## Consent Decree

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- Getinge has now reached an agreement with the FDA concerning a consent decree.
- A consent decree is a legal agreement entered into voluntarily by a company and the U.S. Government and sets forth a process for completing the required improvements.
- The Consent Decree applies to the following Medical Systems Cardiovascular companies, three of which are manufacturing facilities:
  - Atrium Medical Corporation, Hudson, New Hampshire
  - MAQUET Cardiovascular, Wayne, NJ
  - MAQUET Cardiopulmonary, Rastatt and Hechingen, Germany
  - MAQUET Holding, Rastatt, Germany
  - MAQUET Medical Systems, Wayne, NJ
- All other Medical Systems locations inside and outside of the U.S. are not part of this Decree.

**Consent Decree**

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- Atrium will be subject to some manufacturing and delivery restrictions.
- Some products (vascular grafts and surgical meshes) manufactured at Atrium, Hudson, New Hampshire, will be temporarily suspended, once inventory at Medical Systems distribution facilities has been exhausted.
- Certain other products (chest drains, therapeutic infusion catheters and covered stents) have been deemed medically necessary under the Decree and will continue to be made available.
- The Medical Systems facilities in Wayne, Rastatt and Hechingen, which also fall under the decree, will be subject to additional inspections.
- There is no indication that any of the products are unsafe. The Consent Decree does not require Medical Systems to remove, recall or perform corrective actions on any products currently in the market or at Medical Systems' distribution facilities.

- The overall financial impact, excluding the already disclosed remediation cost, related to the consent decree is estimated to amount to SEK 500 million.
- The entire amount will negatively impact the operating profit for 2015.
- The SEK 500 million includes an initial payment of SEK 48 million to the U.S. Government and also covers loss of revenue as a consequence of temporary unavailability of products, training and education of staff and investment in customer relations.
- Not covered in the SEK 500 million is the possibility of an additional payment of SEK 48 million if certain milestones in the enhancement program at Atrium's Hudson, New Hampshire facilities are not completed within six months of the first payment.
- Details of the Consent Decree are posted at [www.atriummed.com/consentdecree](http://www.atriummed.com/consentdecree)

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# Q&A

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## Forward-looking Information

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This document contains forward-looking information based on the current expectations of the Getinge Group's management. Although management deems that the expectations presented by such forward-looking information are reasonable, no guarantee can be given that these expectations will prove correct. Accordingly, the actual future outcome could vary considerably compared with what is stated in the forward-looking information, due to such factors as changed conditions regarding business cycles, market and competition, changes in legal requirements and other political measures, and fluctuations in exchange rates.

# Thank you!

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**GETINGE GROUP**

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Getinge Group is a global leading medical technology company that operates in the areas of surgery, intensive care, infection control, care ergonomics and wound care. Getinge Group has more than 15,000 employees in over 40 countries and generates sales exceeding SEK 25 billion (2013). The Group is divided into three business areas: Medical Systems, Extended Care and Infection Control and operates under the brands of Maquet, ArjoHuntleigh and Getinge.