GETINGE GROUP

Press Release

Göteborg 2015-02-03

Medical Systems business area reaches agreement concerning Consent Decree with U.S. Food and Drug Administration

Getinge Group announced today that its Medical Systems business area has reached an agreement concerning a Consent Decree with the U.S. Food and Drug Administration (FDA). This voluntary agreement establishes a framework that provides assurances to FDA that Medical Systems will complete the improvements currently underway to strengthen its quality management system.

Under the terms of the Consent Decree that was approved by a federal judge in New Hampshire on February 3, 2015, certain products manufactured at Medical Systems' Atrium Medical Corporation business unit based in Hudson, New Hampshire will be temporarily suspended while corrections are being made. These products will be temporarily unavailable, once existing inventory located at Medical Systems' distribution facilities has been exhausted.

Atrium specializes in manufacturing medical devices for the treatment of coronary and vascular disease, tracheal bronchial management, chest trauma, hernia and soft tissue injury.

Certain products currently manufactured by Atrium have been deemed medically necessary under the Decree and will continue to be made available to customers inside and outside of the United States.

Operations at three Medical Systems facilities that also fall under the decree – Wayne, New Jersey and Rastatt and Hechingen, Germany – will be subject to additional inspections, but will continue to produce and distribute products globally. All other Medical Systems manufacturing locations inside and outside of the U.S. are not part of this Decree.

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.

"We have learned from this experience, and this agreement with the FDA provides us with a clear path forward," said Johan Malmquist, CEO Getinge Group. "We have taken this situation very seriously and have committed substantial investments into the quality management system. The remediation work is well underway and has already led to significant improvements."

Financial consequences of the Consent Decree

The overall financial impact, excluding the remediation costs, related to the Consent Decree is estimated to amount to SEK 500 million and will have a negative impact on the operating profit for 2015.

The amount 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.

Remediation costs

As previously disclosed, Getinge has committed SEK 995 million related to the remediation program for strengthening the quality management system within Medical Systems, which was recognized during 2014. The goal is to conclude the remediation program by the middle of 2016.

Background

Temporarily unavailable products include certain vascular grafts and surgical meshes manufactured at Atrium's facilities in Hudson, NH. These restrictions do not apply to vascular grafts that are manufactured at other facilities and sold under the brand names of Hemashield, Intergard, Fusion and Exxcel Soft.

Products available under a Certificate of Medical Necessity include chest drains, local therapeutic infusion catheters, and covered stents.

A Consent Decree is a legal agreement entered into voluntarily by a company and the U.S. Government. A Consent Decree sets forth the terms that the parties agree are needed to resolve FDA quality system related observations.

Medical Systems has created a web site to keep its customers and others informed of this matter. For more information about the Consent Decree and updates on Medical System's progress, visit: www.atriummed.com/consentdecree

This announcement will be followed by a conference call tomorrow, February 4, at 8.00 AM CET, hosted by Johan Malmquist, CEO Getinge Group.

Conference Call

To participate, please call:

Sweden: +46 (0)8 5352 6408

UK: +44 (0)20 3427 1918

US: +1 646 254 3360

Passcode: 2760368

Agenda

7.45 am	*Call the conference number*
8.00 am	*Introduction*
8.30 am	*Q&A*
9.00 am	*End of conference*

During the telephone conference, a presentation will be held. To access the presentation, please use this link:

http://www.livemeeting.com/cc/premconfeurope/join?id=2760368&role=attend&pw=pw8190

A recorded version of the conference will be available from 12:00 on February 4 until February 11 at the following numbers:

Sweden: +46 (0)8 5051 3897

UK: +44 (0)20 3427 0598

US: +1 347 366 9565

Passcode: 2760368

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About Getinge Group

The 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. The Group is divided into three business areas: Extended Care, Infection Control and Medical Systems, and operates under the brands ArjoHuntleigh, Getinge and Maquet.