

# GETINGE GROUP

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## ***Getinge receives warning letter from the FDA concerning its production unit in Wayne***

Getinges production unit in Wayne, New Jersey, US, has received a warning letter from the US FDA (Food and Drug Administration). The warning letter originates from an inspection performed by the authority on the Wayne plant during the spring of 2010. The FDAs observations and remarks relate to the manufacture of vascular grafts. Because the operation in Wayne is also involved in the production of some of the Groups cardiac surgery products, these products will also be affected by the action, since the warning letter is addressed to the production company as such. The warning letter points to two cases of insufficient documentation. The letter also pointed to deficiencies in the information provided in conjunction with a product recall implemented in 2006. A dedicated task force has already been assembled and will work in a focused manner to rectify the deficiencies in the procedures and processes that were observed by the FDA.

During the period the warning letter is in force, the production unit in Wayne will not be granted product approval for newly developed products that require PMA (Premarket Approval), a requirement for the approval of Class 3 products. In addition, the granting of new certificates to foreign Governments may be affected. In the present situation, no products are affected by this limitation and manufacturing and sales of all existing products included in the Wayne units product range may continue without restrictions.

The production unit in Wayne has a long history of developing and manufacturing high-quality products. The Group and Medical Systems, the business area to which the production unit belongs, take an extremely serious view of the situation that has arisen. The necessary resources will be assigned to swiftly resolve the observed deficiencies. The FDA will be kept informed of the actions Getinge intend to take and when the observed deficiencies can be regarded as being rectified.

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GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. ArjoHuntleigh focuses on patient mobility and wound management solutions. GETINGE provides solutions for infection control within healthcare and contamination prevention within life sciences. MAQUET specializes in solutions, therapies and products for surgical interventions and intensive care.

The information is such that Getinge AB must disclose in accordance with the Swedish Securities Market Act and/or the Financial Instruments Trading Act.