

Datascope, a subsidiary of Getinge, receives a warning letter from the US Food and Drug Administration (FDA) at the Mahwah site in the US

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Gothenburg, Sweden

Getinge's production site in Mahwah, New Jersey, US, has received a warning letter from the US Food and Drug Administration. The warning letter originates from routine inspections during 2018 of the Datascope facilities in Mahwah and Fairfield.

FDA's observations are related to procedures and processes linked to requirements on supplier control, design controls and changes, and the corrective and preventive actions (CAPA) procedure. Prior to the 2018 FDA inspection, the company self-identified the deficiencies through internal audit performed by Getinge. Since the end of 2017 a remediation plan has been in place and to resolve the deficiencies in the procedures and processes that were consistent with the FDA inspection. Based on current assessment, net sales and financial impact related to corrections of the findings are expected to be non-material. Production capacity is not deemed to be impacted by the inspection results. There are no known adverse events associated with serious injury or death.

As earlier communicated Getinge's production unit at Datascope in Fairfield received a warning letter from the FDA in September 2018. The warning letter originated from an inspection by the FDA during spring 2018. As in Mahwah, a dedicated team is working on a correction plan since an internal inspection in November 2017. Getinge has submitted an action plan, including activities and a related schedule, to the FDA. Financial impact related to Fairfield observations are not expected to be material. The warning letters will remain open until the corrections have been verified by the agency.

Conference call

A conference call will be hosted by Mattias Perjos, President & CEO on Thursday February 7, 2019, at 4.45 p.m. CET.

Link to presentation and conference call details: <https://financialhearings.com/event/11936>

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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 first-hand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving the every-day life for people, today and tomorrow.