

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

STERIS Corporation
5960 Heisley Road
Mentor
Ohio
44060
USA

Holds Certificate No:

FM 75837

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacturing, distribution and servicing of sterile processing equipment, sterility assurance monitoring products, infection prevention systems and sterilant and disinfectant chemical products for use with equipment for the sterilization and/or high level disinfection of medical devices. The servicing of surgical lights, surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus and accessories.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-10-21

Latest Revision Date: 2018-12-19

Effective Date: 2018-12-19

Expiry Date: 2021-12-18

Page: 1 of 2



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Certificate No: **FM 75837**

Location	Registered Activities
STERIS Corporation 9325 Pinecone Drive Mentor Ohio 44060 USA	The Manufacture and distribution of sterility assurance monitoring products and sterilization accessories such as incubators, pouches, and trays.
STERIS Corporation 6100 Heisley Road Mentor Ohio 44060 USA	The manufacture and distribution of sterilant and disinfectant chemical products for use with equipment for sterilization and/or disinfection of medical devices.
STERIS Corporation 6515 Hopkins Road Mentor Ohio 44060 USA	The manufacture of sterile processing systems, sterilant and disinfectant chemical products for use with equipment for sterilization and/or disinfection of medical devices.
STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA	The design, development, manufacturing, distribution and servicing of sterile processing equipment, sterility assurance monitoring products, infection prevention systems and sterilant and disinfectant chemical products for use with equipment for the sterilization and/or high level disinfection of medical devices. The servicing of surgical lights, surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus and accessories.

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Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.