



## 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 highlevel disinfection of medical devices. The design and servicing of surgical lights, surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus and accessories.

iang Conada

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-10-21 Latest Revision Date: 2020-05-12

bsi.



Effective Date: 2018-12-19 Expiry Date: 2021-12-18

Page: 1 of 2

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.

## Certificate No: **FM 75837**

Location

**Registered Activities** 

The Manufacture and distribution of sterility assurance monitoring products and sterilization accessories such as incubators, pouches, and trays.
The manufacture and distribution of sterilant and disinfectant chemical products for use with equipment for sterilization and/or disinfection of medical devices.
The Manufacture and distribution of sterility assurance monitoring products and sterilization accessories such as incubators, pouches, and trays. The design of surgical lights, surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus and accessories
The manufacturing of sterility assurance monitoring products.
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 design and servicing of surgical lights, surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus and accessories.
_

Original Registration Date: 2003-10-21 Latest Revision Date: 2020-05-12 Effective Date: 2018-12-19 Expiry Date: 2021-12-18

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.