

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 Number:

FM 75837

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

The design, development, manufacture, distribution, and servicing of sterile processing equipment, sterility assurance monitoring products, infection prevention systems and sterilant, disinfectant chemical products for use with equipment for the sterilization and/or high-level disinfection of medical devices, and thermal regulating systems.

The design and servicing of surgical lights, and surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus.

The distribution of products manufactured by US Endoscopy.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2003-10-21

Latest Revision Date: 2025-04-10

Effective Date: 2024-12-19

Expiry Date: 2027-12-18

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...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

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. The distribution of products manufactured by US Endoscopy.
STERIS Corporation 6515 Hopkins Road Mentor Ohio 44060 USA	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, thermal regulating systems and accessories.
Steris Corporation 11457 Melrose Ave Franklin Park Illinois 60131 USA	The manufacture of sterility assurance monitoring products.
STERIS Solutions Limited Chancery House Ryans Way Watermead Business Park Syston Leicester LE7 1PF United Kingdom	The installation and servicing of washer disinfecter equipment, sterilization equipment, endoscope reprocessing equipment, and surgical equipment. The distribution of products used in healthcare.

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Registered Activities

The design, development, manufacture, 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, and surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus, and accessories.

The manufacture and servicing of thermal regulating systems.



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