By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

STERIS Corporation
5960 Heisley Road
Mentor
Ohio
44060
USA

Facility ID Number: F000422

Holds Certificate No: **MDSAP 685944**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-12-19 Effective Date: 2025-07-10 Expiry Date: 2027-12-18

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 685944**

Registered Scope:

The design, development, manufacture, distribution, installation 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, installation 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.

Original Registration Date: 2018-12-19 Effective Date: 2025-07-10 Expiry Date: 2027-12-18

Certificate No: **MDSAP 685944**

Location	Registered Activities
STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA Facility ID Number: F000422	The design, development, manufacture, distribution, installation 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, installation and servicing of surgical lights, and surgical tables, ceiling mounted support columns, warming cabinets, surgical exhaust apparatus.
STERIS Corporation 9325 Pinecone Drive Mentor Ohio 44060 USA Facility ID Number: F000422	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 Facility ID Number: F000422	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 Facility ID Number: F000422	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.

Original Registration Date: 2018-12-19 Effective Date: 2025-07-10 Expiry Date: 2027-12-18