



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: STERIS Corporation

5960 Heisley Road

Mentor Ohio 44060 USA

DUNS Number: 17-736-0039

Holds certificate No: MDSAP 685944

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1-SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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

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...making excellence a habit."



This certificate remains the property of BSI and shall be returned immediately upon request. To be read in conjunction with the scope above or the attached appendix.

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Location	Registered Activities
STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA DUNS Number: 17-736-0039	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.
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.

Original Registration Date: 2018-12-19 Effective Date: 2018-12-19 Expiry date: 2021-12-18

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