

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

STERIS MEXICO, S. de R.L. de C.V.
Avenida Avante 790
Parque Industrial Guadalupe
Guadalupe
Nuevo León
67190
Mexico

Facility ID Number: F001940

Holds Certificate No:

MDSAP 685950

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; 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, manufacture and Distributor of Steam Sterilizers and the manufacture and distribution of VHP Sterilizers for healthcare and life science institutions.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-22

Effective Date: 2021-10-22

Expiry Date: 2024-10-21



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 1

...making excellence a habit.™