Certificate of Registration

By Royal Charter

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

DUNS Number: 81-311-6209

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 [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

Design and development, manufacture and distribution of infection control equipment (Steam, EO and VHP sterilizers) for healthcare and life science institutions.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2018-10-22 Effective Date: 2018-10-22 Expiry date: 2021-10-21

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

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