



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Symmetry Surgical, Inc.

3034 Owen Drive

Antioch Tennessee 37013 USA

Facility ID Number: F000433

Holds Certificate No: MDSAP 691125

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: 2019-03-22 Effective Date: 2025-03-22 Expiry Date: 2028-03-21

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

Certificate No: MDSAP 691125

Registered Scope:

Design and develop, manufacture, service, and distribution of neurosurgical instruments, electrosurgical, manual surgical instruments and accessories in the following families: Orthopaedic, Laparoscopic and Endoscopic, Dental, Ear, Nose and Throat, Obstetrical, General Surgery. These include non-sterile reusable surgical instruments both handheld and non-handheld, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, retractors systems, and sterilization containers; Sterile disposable surgical products, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, suction coagulators, and retractors systems, ESU Generators, cautery, surgical lights, nerve locator, Cholangiogram Catheter, Ophthalmic burrs and handle, and Smoke evacuation system and accessories.



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