

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Synaptive Medical Inc.
5055 Satellite Drive, Unit #1
Mississauga
Ontario
L4W 5K7
Canada

Facility ID Number: F000434

Holds Certificate No:

MDSAP 674127

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

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: 2018-10-02

Effective Date: 2025-09-11

Expiry Date: 2027-05-07



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 674127**

Registered Scope:

Design and development, production, installation, and servicing of: surgical planning software, surgical device and tool tracking systems, surgical device and tool positioning systems, optical surgical visualization systems. Design and development, manufacture, installation, and servicing of Picture Archiving/Communication System (PACS) with data management software, used in the storage, retrieval and presentation of radiographic and other images. Design and development, manufacture, installation and servicing of Magnetic Resonance Imaging (MRI) Systems including related Software and MRI coils.

Design and development, manufacture, and servicing of quality control support tools for MRI, CT, Ultrasound, and X-Ray.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.