

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Synaptive Medical Inc.  
555 Richmond Street West  
Suite 800  
Toronto  
Ontario  
M5V 3B1  
Canada

Facility ID Number: F000434

Holds Certificate No:

**MDSAP 674127**

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; 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

Please see scope page.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-02

Effective Date: 2021-05-08

Expiry Date: 2024-05-07



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 2

...making excellence a habit.™

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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Page: 2 of 2

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

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.