

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

Holds Certificate Number:

FM 655901

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-05-16

Latest Revision Date: 2024-02-27

Effective Date: 2024-05-08

Expiry Date: 2027-05-07

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