EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 723819 R000

Manufacturer: Synaptive Medical Inc.

Address:
555 Richmond Street West
Suite 800
Toronto
Ontario
M5V 3B1
Canada

Single Registration Number: CA-MF-000010705

EU Authorised Representative: Medical Device Safety Service GmbH (MDSS)

Address:
Schiffgraben 41
Hanover
30175
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-06-17**

Current Issue Date: **2023-05-18**

Starting Validity Date: **2023-05-18**

Expiry Date: **2026-06-16**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Trackable Suction	Class IIa
Modus Plan	Class IIa
Reusable Pointer Instruments	Class Ir

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-06-17	3142839	Issued.
2022-03-11	3643368	Amended – Addition of the manufacturer's Single Registration Number (CA-MF-000010705) Amended – Addition of subcontractors: Arch Medical Solutions – Sparta LLC, Northern Digital, Inc. Supplemented – Addition of Trackable Suction device
2022-06-27	3484275	Supplemented – Addition of Modus Plan device
Current	30000443	Amended – Replacement of device name "BrightMatter Pointer" with device category "Reusable Pointer Instruments"

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