



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cerenovus, Inc. 325 Paramount Drive

Raynham Massachusetts 02767-0350 USA

Holds Certificate No:

FM 72499

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

The design, development, manufacture, including packaging, sterilization and inspection, and distribution of single-use infusion/microcatheters and intermediate catheters, balloon catheters, guiding catheters, steerable guidewires, thrombectomy devices, intracranial vascular stents, and vascular occlusion devices.

The manufacture, including packaging, sterilization, and inspection of single use sterile catheters for intracranial pressure monitors.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-12-24 Latest Revision Date: 2022-05-12 Effective Date: 2021-06-09 Expiry Date: 2024-06-08

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...making excellence a habit."

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Location	Registered Activities
Cerenovus, Inc. 325 Paramount Drive Raynham Massachusetts 02767-0350 USA	The manufacture, including packaging, sterilization and inspection, and distribution of single-use sterile catheters for intracranial pressure monitors, steerable guidewires, intracranial vascular stents, and vascular occlusion devices.
Cerenovus, Inc. Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez Chihuahua C.P. 32574 Mexico	Manufacture, inspection, packaging and labeling of guiding catheters, infusion/microcatheters, and detachable coil systems.
Cerenovus, Inc. 6303 Blue Lagoon Drive, Suite 315 Miami Florida 33126 USA	Design and development of infusion/microcatheters, balloon catheters, guiding catheters, steerable guidewires, intracranial vascular stents, thrombectomy devices, vascular occlusion devices (microcoil systems, pushable coils, and detachable coil systems).
Cerenovus, Inc. 47709 Fremont Blvd Fremont California 94538 USA	Manufacture, inspection, packaging and labeling of microcoil system (microcoils, connecting cables and detachment control boxes), and intracranial vascular reconstruction devices, and thrombectomy devices.
Cerenovus, Inc. 3260 Executive Way Miramar Florida 33025 USA	Manufacture of minimally invasive device for endovascular treatment of vascular diseases, including microcoil systems (device positioning units), infusion/microcatheters and intermediate catheters, guiding catheters and balloon catheters.

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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.