



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

Canada - Medical Devices Regulations – Part 1- SOR 98/282

United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,

21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Lake Region Medical
340 Lake Hazeltine Dr.
Chaska, MN 55318
USA

D-U-N-S: 042296665

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design and Development, Manufacture and Distribution of Sterile and Non-Sterile Guidewires for Vascular and Non-Vascular use, including Guidewires with Electrical Components, Intravascular Catheters, Torque Devices and Biopsy Instruments.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4406)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Certificate Number: MP19.4406 / Rev 1

Certification Granted: 2019 March 05

Effective Date: 2019 March 05

Expiry Date: 2022 March 04



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412

All valid certifications are listed on NSAI's website – www.nsa-inc.com The continued validity of this certificate may be verified under "Approved Client Listing"



Annex to Certificate number: MP19.4406 / Rev 1

Scope of Registration:

The Design and Development, Manufacture and Distribution of Sterile and Non-Sterile Guidewires for Vascular and Non-Vascular use, including Guidewires with Electrical Components, Intravascular Catheters, Torque Devices and Biopsy Instruments.

Activity

Design and Development,
Manufacturing, Distribution

Location

Lake Region Medical
340 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MP19.4406
D-U-N-S: 042296665

Manufacturing, Distribution

Lake Region Medical
305 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MP19.4406/A
D-U-N-S: 042296665

Manufacturing

Lake Region Medical
307 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MP19.4406/B
D-U-N-S: 042296665

Manufacturing, Distribution

Lake Region Medical
304 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MP19.4406/C
D-U-N-S: 042296665

Manufacturing, Distribution,
Warehouse, Service

Lake Region Medical
1234 Lakeview Dr.
Chaska, MN 55318
USA
File No.: MP19.4406/D
D-U-N-S: 042296665

**Verified by:
Operations Manager**