



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

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

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

The Design and Development, Manufacture, Contract Manufacture, and Distribution of Sterile and Non-Sterile Guidewires for Vascular and Non-Vascular use, including Guidewires with Electrical Components, Intravascular Catheters, Stents, Stent Delivery Systems, Torque Devices, Stylets, Biopsy Instruments, Machined Components, and Custom Wire and Tube Products for Medical Applications.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4406)

Approved by:
Kevin D. Mullaney
Chief Executive Officer

Approved by:
Susan Murphy
Risk Management Officer

Registration Number: MD19.4406
Certification Granted: Oct 08, 2008
Effective Date: Aug 10, 2016
Expiry Date: Jul 24, 2019



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



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Annex to Certificate Number: MD19.4406

Scope of Registration :

The Design and Development, Manufacture, Contract Manufacture, and Distribution of Sterile and Non-Sterile Guidewires for Vascular and Non-Vascular use, including Guidewires with Electrical Components, Intravascular Catheters, Stents, Stent Delivery Systems, Torque Devices, Stylets, Biopsy Instruments, Machined Components, and Custom Wire and Tube Products for Medical Applications.

Activity

Location

Design and Development,
Manufacturing, Distribution

Lake Region Medical
340 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MD19.4406

Manufacturing, Distribution

Lake Region Medical
305 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MD19.4406/A

Manufacturing

Lake Region Medical
307 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MD19.4406/B

Manufacturing, Distribution

Lake Region Medical
304 Lake Hazeltine Dr.
Chaska, MN 55318
USA
File No.: MD19.4406/C

Manufacturing, Distribution,
Warehouse, Service

Lake Region Medical
1234 Lakeview Dr.
Chaska, MN 55318
USA
File No.: MD19.4406/D

**Verified by:
Operations Manager**