

NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

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.

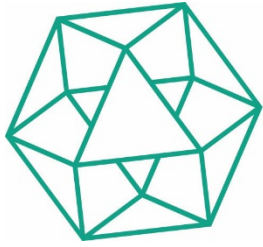
Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4406)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.4406
Certification Granted: October 08, 2008
Effective Date: March 05, 2019
Expiry Date: March 04, 2022





NSAI

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**