



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

**Australia** - Therapeutic Goods (Medical Devices) Regulations, 2002,

☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil** - RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009

**Japan**- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)

**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**

**Facility ID: F003627**

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:

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**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:  
Kevin Mullaney  
Director of Certification

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Certificate Number: MP19.4406 / Rev 2

Certification Granted: 2022/03/05

Effective Date: 2023/05/23

Expiry Date: 2025/03/04



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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.nsaiinc.com](http://www.nsaiinc.com) The continued validity of this certificate may be verified under "Approved Client Listing"



## **Annex to Certificate number: MP19.4406 / Rev 2**

### **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

Manufacturing, Distribution

Manufacturing

Manufacturing, Distribution

Manufacturing, Distribution,  
Warehouse, Service

#### **Location**

Lake Region Medical  
340 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: MP19.4406  
Facility ID: F003627

Lake Region Medical  
305 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: MP19.4406/A  
Facility ID: F003627

Lake Region Medical  
307 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: MP19.4406/B  
Facility ID: F003627

Lake Region Medical  
304 Lake Hazeltine Dr.  
Chaska, MN 55318  
USA  
File No.: MP19.4406/C  
Facility ID: F003627

Lake Region Medical  
1234 Lakeview Dr.  
Chaska, MN 55318  
USA  
File No.: MP19.4406/D  
Facility ID: F003627

**Verified by:  
Director of Certification**