



NSAI

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

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 Management System Regulation

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

**Lake Region Medical
Parkmore West Business Park
Galway
Co. Galway
Ireland**

Facility ID: F001574

The quality management system has been audited against stated criteria above and found to conform to the criteria for the scope listed below:

The Design, Manufacture and Distribution of Sterile and Non-Sterile Interventional Guidewires, Interventional Devices including Catheters and Components

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.3331)


Approved by:
Pamela Burdette Miller
Certification Manager

Certificate Number: MP19.3331 / Rev 2
Certification Granted: 2018/12/12
Effective Date: 2026/04/03
Expiry Date: 2027/12/11



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 and may be verified under "Approved Client Listing"



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Annex to Certificate Number: MP19.3331 / Rev 2

Facility Locations, Scope and Activities

Lake Region Medical

Parkmore West Business Park, Galway, Co. Galway, Ireland

File No.: MP19.3331

Facility ID: F001574

Scope:

The Design, Manufacture and Distribution of Sterile and Non-Sterile Interventional Guidewires, Interventional Devices Including Catheters and Components

Lake Region Medical

Parkmore East Business Park, Galway, Co. Galway, Ireland

File No.: MP19.3331/B

Facility ID: F001574

Scope:

The Design, Manufacture and Distribution of Sterile and Non-Sterile Interventional Guidewires, Interventional Devices Including Catheters and Components

**Verified by:
Certification Manager**