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.
- ☐ Schedule 3 Part 4 – Production Quality Assurance Procedure

Brazil- RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada- Medical Devices Regulations – Part 1- SOR 98/282
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,
- ☐ 21 CFR 821 - Device Tracking

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

Lake Region Medical Ltd.
Butlersland
New Ross
Co Wexford
Ireland
D-U-N-S: 988555595

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

The design & development, manufacture and distribution of sterile and non-sterile guidewires used in peripheral, cardiac and urological applications.

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Eoin Banville
Operations Manager,
Medical Devices

Certificate Number: MP19.3915 /Rev 1
Certification Granted: 2006/06/12
Effective Date: 2018/06/08
Expiry Date: 2021/06/07

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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
The continued validity of this certificate may be verified under "Approved Client Listing