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 System Regulation

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

Lake Region Medical Ltd.
Butlersland
New Ross
Co Wexford
Ireland
Facility ID: F001023

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:

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

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.3915 / Rev 2
Certification Granted: 2018/06/08
Effective Date: 2022/06/08
Expiry Date: 2024/06/07

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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