



NSAI

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

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
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:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.3915 / Rev 1
Certification Granted: 2018/06/08
Effective Date: 2021/06/08
Expiry Date: 2022/06/07



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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"