



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:

Brivant Limited

Parkmore West Business Park

Galway

Co. Galway

Ireland

Facility ID: F001574

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, 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)

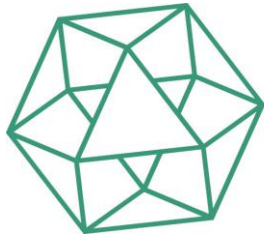
Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.3313 / Rev 1
Certification Granted: 2018/12/12
Effective Date: 2021/12/12
Expiry Date: 2024/12/11



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



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Annex to Certificate Number: MP19.3331 / Rev 1

Scope of Registration:

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

Activity

Head Quarters, Administration,
Design, Manufacturing,
Distribution

Distribution

Location

Brivant Limited
Parkmore West Business Park
Galway
Co. Galway
Ireland
File No.: MP19.3331
Facility ID: F001574

Brivant Limited
R&D Innovation Centre
Unit 4 Claregalway Corporate Park
Claregalway
Co. Galway
Ireland
File No.: MP19.3331/A
Facility ID: F001574

**Verified by:
Operations Manager**