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. 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

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

Xeridiem Medical Devices
4700 South Overland Drive
Tucson, AZ 85714-3430
USA

Facility ID: F001586

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 and Development, Manufacture, and Distribution of Packaged Sterile and Bulk Non-Sterile Catheters, Tubing and Tubing Sets, Drainage Devices, Speculums, Manual Radionuclide Applicator System, and Stoma Devices for Cardiovascular, Peripheral, Urological, Obstetrical, Gynecological, Oncological, Therapeutic Hypothermia and Enteral Feeding Applications, Surgical Instrument and Cardiac Leads.

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.2170 / Rev 1
Certification Granted: 2018/12/18
Effective Date: 2021/12/18
Expiry Date: 2024/12/17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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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