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
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 Management 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

The quality management system has been audited against stated criteria above and found to conform to the criteria for the scope listed 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:
Pamela Burdette Miller
Certification Manager

Certificate Number: MP19.2170 / Rev 2
Certification Granted: 2018/12/18
Effective Date: 2026/03/17
Expiry Date: 2027/12/17

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All valid certifications are listed on NSAI's website – www.nsaiinc.com and may be verified under "Approved Client Listing"