



# NSAI

## 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 System Regulation

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

**Xeridiam 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:  
Kevin Mullaney  
Director of Certification

Certificate Number: MP19.2170 / Rev 1

Certification Granted: 2018/12/18

Effective Date: 2024/12/18

Expiry Date: 2027/12/17



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