

# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

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

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

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**The Design and Development, Manufacture, and Distribution of Packaged Sterile and Bulk Non-Sterile Catheters, Tubing and Tubing Sets, Drainage Devices, and Stoma Devices for Cardiovascular, Peripheral, Urological, and Enteral Feeding Applications, Surgical Instruments and Cardiac Leads.**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

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

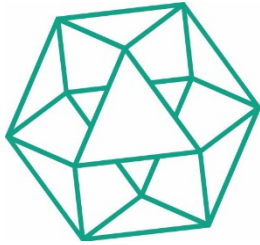
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Registration Number: MD19.2170  
Certification Granted: July 20, 2004  
Effective Date: December 18, 2018  
Expiry Date: December 17, 2021



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National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



# 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. 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:

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

**D-U-N-S: 024182514**

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:

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**The Design and Development, Manufacture, and Distribution of Packaged Sterile and Bulk Non-Sterile Catheters, Tubing and Tubing Sets, Drainage Devices, and Stoma Devices for Cardiovascular, Peripheral, Urological, and Enteral Feeding Applications, Surgical Instruments and Cardiac Leads.**

Approved by:  
Geraldine Larkin  
Chief Executive  
Officer

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

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



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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.nsa-inc.com](http://www.nsa-inc.com)  
The continued validity of this certificate may be verified under "Approved Client Listing"