



# 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

**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:

**Medivators Inc.**

**14605 28th Avenue North**

**Minneapolis, MN 55447**

**USA**

**Facility ID: F001582**

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, Manufacture and Distributor of Automatic Endoscope Reprocessing Equipment, Sterilants, Detergents and High Level Disinfectants. The Manufacture and Distribution of Endoscopic Irrigation Pumps and Insufflators. The Manufacture of Dialyzer Reprocessing Systems, Hemodialysis Concentrates, Hemodialyzers, Hemofilters, Hemoconcentrators and Water Filters. The Service of Automatic Endoscope Reprocessing Equipment and Endoscopic Irrigation Pumps and Insufflators.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.2990)**

Approved by:

Kevin Mullaney

Director of Certification

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Certificate Number: MP19.2990 / Rev 3

Certification Granted: 2019/03/29

Effective Date: 2023/07/25

Expiry Date: 2025/03/28



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



# NSAI

## Annex to Certificate Number: MP19.2990 / Rev 3

### Scope of Registration:

**The Design, Manufacture and Distributor of Automatic Endoscope Reprocessing Equipment, Sterilants, Detergents and High Level Disinfectants. The Manufacture and Distribution of Endoscopic Irrigation Pumps and Insufflators. The Manufacture of Dialyzer Reprocessing Systems, Hemodialysis Concentrates, Hemodialyzers, Hemofilters, Hemoconcentrators and Water Filters. The Service of Automatic Endoscope Reprocessing Equipment and Endoscopic Irrigation Pumps and Insufflators.**

### Activity

Headquarters, Administration, Design & Development, Manufacturing, Distribution, Servicing, Purchasing

Manufacturing

Warehouse, Distribution

### Location

Medivators Inc.  
14605 28th Avenue North  
Minneapolis, MN 55447  
USA  
File No.: MP19.2990  
Facility ID: F001582

Medivators Inc.  
14905 28th Avenue North  
Minneapolis, MN 55447  
USA  
File No.: MP19.2990/B  
Facility ID: F001582

Medivators Inc.  
14585 Northdale Boulevard  
Rogers, MN 55374  
USA  
File No.: MP19.2990/D  
Facility ID: F001582

**Verified by:  
Director of Operations**