



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

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:

The Design, Manufacture, Distribution, Installation and Service of Automatic Endoscope Reprocessing Equipment, Sterilants, Detergents and High Level Disinfectants, Dialyzer Reprocessing Systems, Hemodialysis Concentrates, Hemodialyzers, Hemofilters and Hemoconcentrators, Water Filters 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

Certificate Number: MP19.2990 / Rev 2

Certification Granted: 2019/03/29

Effective Date: 2022/06/14

Expiry Date: 2025/03/28



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 The continued validity of this certificate may be verified under "Approved Client Listing"



NSAI

Annex to Certificate number: MP19.2990 / Rev 1

Scope of Registration:

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

Activity

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

Location

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

Manufacturing

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

Administration, Servicing, Installation

Medivators Inc.
9800 59th Avenue North
Plymouth, MN 55442
USA
File No.: MP19.2990/C
Facility ID: F001582

Warehouse, Distribution

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

**Verified by:
Director of Operations**