



NSAI

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

The National Standards Authority of Ireland certifies that:

Medivators Inc.
14605 28th Avenue North
Minneapolis, MN 55447
USA

has been assessed and deemed to comply with the requirements of the above standard 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. MD19.2990)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.2990
Certification Granted: September 27, 1999
Effective Date: March 29, 2019
Expiry Date: March 28, 2022





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Annex to Certificate Number: MD19.2990

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

Location

Headquarters, Design &
Development, Manufacturing,
Distribution, Service

Medivators Inc.
14605 28th Avenue North
Minneapolis, MN 55447
USA
File No.: MD19.2990

Manufacturing

Medivators Inc.
14550 28th Avenue North
Minneapolis, MN 55447
USA
File No.: MD19.2990/A

Manufacturing

Medivators Inc.
14905 28th Avenue North
Minneapolis, MN 55447
USA
File No.: MD19.2990/B

Administration

Medivators Inc.
6655 Wedgewood Road
Suite 160
Maple Grove, MN 55311
USA
File No.: MD19.2990/C

**Verified by:
Operations Manager**



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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

D-U-N-S: 068199363

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:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.2990 / Rev1

Certification Granted: 2019/03/29

Effective Date: 2019/03/29

Expiry Date: 2022/03/28



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"



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Annex to Certificate number: MP19.2990 / Rev1

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, Service

Location

Medivators Inc.
14605 28th Avenue North
Minneapolis, MN 55447
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File No.: MP19.2990
D-U-N-S: 068199363

Manufacturing

Medivators Inc.
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