

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: Kevin Mullaney Director of Certification

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Registration Number: MD19.2990 Certification Granted: September 27, 1999 Effective Date: March 29, 2022 Expiry Date: March 28, 2025



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



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, Medivators Inc. Manufacturing, Distribution, Servicing, 14605 28th Avenue North Purchasing Minneapolis, MN 55447 USA File No.: MD19.2990 Manufacturing Medivators Inc. 14550 28th Avenue North Minneapolis, MN 55447 USA File No.: MD19.2990/A Medivators Inc. Manufacturing 14905 28th Avenue North Minneapolis, MN 55447 USA File No.: MD19.2990/B Medivators Inc. Administration, Servicing, Installation 9800 59th Avenue North Plymouth, MN 55442 USA File No.: MD19.2990/C Warehouse, Distribution Medivators Inc. 14585 Northdale Boulevard Rogers, MN 55374 USA File No.: MD19.2990/D Verified by: **Director of Certification**