

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 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. MD19.2990)

Approved by: Kevin Mullaney Director of Certification

Registration Number: MD19.2990

Certification Granted: September 27, 1999

Effective Date: July 25, 2023 Expiry Date: March 28, 2025





Annex to Certificate Number: MD19.2990

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.: MD19.2990

Medivators Inc.

14905 28th Avenue North Minneapolis, MN 55447

USA

File No.: MD19.2990/B

Medivators Inc.

14585 Northdale Boulevard

Rogers, MN 55374

USA

File No.: MD19.2990/D

Verified by: Director of Certification