

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

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 Including Leak Tester Accessories, Sterilants, Detergents and High Level Disinfectants, Dialyzer Reprocessing Systems, Hemodialysis Concentrates, Hemodialyzers, Hemofilters and Hemoconcentrators, Water Filters and Service of Endoscopic Irrigation Pumps and Insufflators. Provision of hydrogen peroxide/peracetic acid contract processing services in accordance with ISO 14937:2009.

Additional sites covered under this multi-site certification are listed on the Annex (File No.MD19.2990)

Approved by: Kevin D. Mullaney Chief Executive Officer Approved by: Susan Murphy Risk Management Officer Busan Wanphy

Registration Number: MD19.2990

Certification Granted: Sep 27, 1999

Effective Date: Aug 11, 2015 Expiry Date: Feb 24, 2018 0



Annex to Certificate File No: MD19.2990

## **Scope of Registration:**

The Design, Manufacture, Distribution, Installation and Service of Automatic Endoscope Reprocessing Equipment Including Leak Tester Accessories, Sterilants, Detergents and High Level Disinfectants, Dialyzer Reprocessing Systems, Hemodialysis Concentrates, Hemodialyzers, Hemofilters and Hemoconcentrators, Water Filters and Service of Endoscopic Irrigation Pumps and Insufflators. Provision of hydrogen peroxide/peracetic acid contract processing services in accordance with ISO 14937:2009.

Activity	Location
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Design & Development, Manufacturing, Distribution, Service Medivators Inc. 14605 28<sup>th</sup> Avenue North Minneapolis, MN 55447

USA

File No.: MD19.2990

Manufacturing Medivators Inc.

14550 28<sup>th</sup> Avenue North Minneapolis, MN 55447

USA

File No.: MD19.2990/A

Manufacturing Medivators Inc.

14905 28<sup>th</sup> Avenue North Minneapolis, MN 55447

USA

File No.: MD19.2990/B

Verified by: Operations Manager