

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

The National Standards Authority of Ireland certifies that: **Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303**

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 and Development, Manufacture, and Distribution of Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile and non-sterile Tubing, Tubing Sets, Irrigation Pumps, Insufflators, Endoscopy Procedure Kits and Accessories.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4716)

Approved by: Kevin Mullaney Director of Certification

Registration Number: MD19.4716 Certification Granted: May 30, 2012

Effective Date: May 16, 2025 Expiry Date: May 15, 2028





Annex to Certificate Number: MD19.4716

Facility Locations, Scope and Activities

Medivators Inc. 3150 Pollok Dr., Conroe, TX 77303 USA File No: MD19.4716

Scope: The Design and Development, Manufacture and Distribution of Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves and Sterile Tubing sets.

Activities: Design & Development, Manufacturing

Medivators Inc. 3101 Pollok Dr., Conroe, TX 77303 USA File No.: MD19.4716/A

Scope: The Design and Development of Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile and Non-Sterile Tubing Sets, and Endoscopy Procedure Kits and Accessories.

Activities: Administration, Design & Development

Medivators Inc.
501 North Farm to Market 3083 Rd E, Conroe, TX 77303 USA
File No.: MD19.4716/B

Scope: The Manufacture of components for Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile and Non-sterile Tubing Sets, and Endoscopy Procedure Kits and Accessories.

Activities: Manufacturing



Annex to Certificate Number: MD19.4716

Facility Locations, Scope and Activities

Medivators Inc. 750 Conroe Park North, Conroe, TX 77303 USA File No: MD19.4716/C

Scope: The Manufacturing of Non-sterile Tubing Sets. The Packaging and Distribution of Medical Devices used in Endoscopy Procedures and General Surgery including Endoscopy Procedure Kits and Accessories.

Activities: Manufacturing, Packaging, Distribution

Medivators Inc. 3155 Conroe Park North, Conroe, TX 77303 USA File No: MD19.4716/D

Scope: The Storage and Distribution of Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile and Non-sterile Tubing Sets, Irrigation Pumps, Insufflators, and Endoscopy Procedure Kits. The Manufacturer of Irrigation Pumps & Insufflators.

Activities: Manufacturing, Distribution

Verified by:
Director of Certification