

# 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 nonsterile 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 28, 2024 Expiry Date: May 15, 2025



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## 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