

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 Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits.

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

Approved by: Kevin Mullaney Director of Certification

Koning

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

Effective Date: May 16, 2022 Expiry Date: May 15, 2025





Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits.

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HQ, Administration, Design & Development, Manufacturing, Distribution

Design & Development

Administration, Manufacturing

Manufacturing, Distribution

Location

Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303

USA

File No.: MD19.4716

Medivators Inc. 3101 Pollok Dr. Conroe, TX 77303

USA

File No.: MD19.4716/A

Medivators Inc.

501 North Farm to Market 3083 Rd E

Conroe, TX 77303

USA

File No.: MD19.4716/B

Medivators Inc.

750 Conroe Park North

Conroe, TX 77303

USA

File No: MD19.4716/C



Annex to Certificate Number: MD19.4716

Scope of Registration:

The Design and Development, Manufacture, and Distribution of Medical Devces used in Endoscopy Procedures and General Surgery including Disposable Valves, Sterile Tubing Sets, Endoscopy Cuffs, Endoscopy Procedure Kits.

Activity

Location

Distribution

Medivators Inc. 3155 Conroe Park North Conroe, TX 77303 USA

File No: MD19.4716/D

Verified by: Operations Manager