

Certificate of Registration of Quality Management System to ISO 13485:2016

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,

Schedule 3 Part 1 (excluding Part 1.6) − Full Quality Assurance Procedure

Canada - Medical Devices Regulations - Part 1- SOR 98/282

United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303 USA

Facility ID: F001583

has been assessed and deemed to comply with the requirements of the above standard and regulations 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 Tubing Sets and Endoscopy Procedure Kits.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4716)

Approved by: Kevin Mullaney

Director of Certification

Certificate Number: MP19.4716 / Rev 2 Certification Granted: 2019/05/16

Effective Date: 2023/02/21 Expiry Date: 2025/05/15







Annex to Certificate Number: MP19.4716 / Rev 2

Scope of Registration:

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

| Activity Location Location |
|----------------------------|
|----------------------------|

HQ, Administration, Design & Development, Manufacturing, Distribution

Medivators Inc. 3150 Pollok Dr. Conroe, TX 77303

USA

File No: MP19.4716 Facility ID: F001583

Design & Development

Medivators Inc. 3101 Pollok Dr. Conroe, TX 77303

USA

File No.: MP19.4716/A Facility ID: F001583

Administration, Manufacturing

Medivators Inc.

501 North Farm to Market 3083 Rd E

Conroe, TX 77303

USA

File No.: MP19.4716/B Facility ID: F001583

Manufacturing, Distribution

Medivators Inc.

750 Conroe Park North Conroe, TX 77303

USA

File No: MP19.4716/C Facility ID: F001583



Annex to Certificate Number: MP19.4716 / Rev 1

Scope of Registration:

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

Activity Location

Distribution

Medivators Inc. 3155 Conroe Park North Conroe, TX 77303 USA File No: MP19.4716/D

File No: MP19.4/16/D Facility ID: F001583

Verified by: Director of Certification