



NSAI

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

Brazil - RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009

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

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

☒ 21 CFR 820 – Quality System Regulation

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 and non-sterile Tubing, tubing sets, Irrigation Pumps, Insufflators, 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 1

Certification Granted: 2019/05/16

Effective Date: 2025/05/16

Expiry Date: 2028/05/15



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National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



Annex to Certificate Number: MP19.4716 / Rev 1

Facility Locations, Scope and Activities

Medivators Inc.
3150 Pollok Dr., Conroe, TX 77303 USA
File No: MP19.4716
Facility ID: F001583

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.: MP19.4716/A
Facility ID: F001583

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.

Activities: Administration, Design & Development

Medivators Inc.
501 North Farm to Market 3083 Rd E, Conroe, TX 77303 USA
File No.: MP19.4716/B
Facility ID: F001583

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.

Activities: Manufacturing



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Facility Locations, Scope and Activities

Medivators Inc.
750 Conroe Park North, Conroe, TX 77303 USA
File No: MP19.4716/C
Facility ID: F001583

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.

Activities: Manufacturing, Packaging, Distribution

Medivators Inc.
3155 Conroe Park North, Conroe, TX 77303 USA
File No: MP19.4716/D
Facility ID: F001583

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