

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

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 Tubing Sets, Endoscopy Cuffs and Endoscopy Procedure Kits.

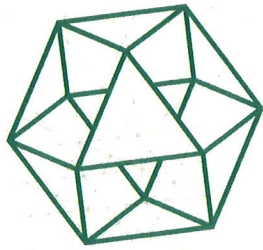
Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4716)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4716 / Rev 1
Certification Granted: 2019/05/16
Effective Date: 2022/05/16
Expiry Date: 2025/05/15



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website – www.nsaiinc.com The continued validity of this certificate may be verified under "Approved Client Listing"



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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, Endoscopy Cuffs and Endoscopy Procedure Kits.

Activity

HQ, Administration, Design & Development, Manufacturing, Distribution

Design & Development

Administration, Manufacturing

Manufacturing, Distribution

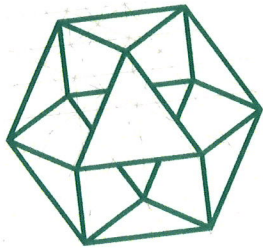
Location

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

Medivators Inc.
3101 Pollok Dr.
Conroe, TX 77303
USA
File No.: MP19.4716/A
Facility ID: F001583

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

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



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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, Endoscopy Cuffs and Endoscopy Procedure Kits.

Activity

Distribution

Location

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

**Verified by:
Operations Manager**