

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medivators Inc.
3150 Pollok Drive
Conroe
Texas
77303
USA

Facility ID Number: F008421

Holds Certificate No:

MDSAP 832502

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

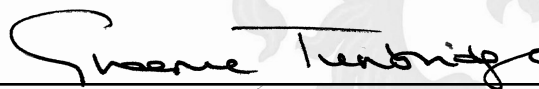
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

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

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-09-08

Effective Date: 2025-09-08

Expiry Date: 2028-05-15



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

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Certificate No: **MDSAP 832502**

Registered Scope:

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.

Transfer from NSAI

Certificate number: MP19.4716 / Rev 1



Original Registration Date: 2025-09-08

Effective Date: 2025-09-08

Expiry Date: 2028-05-15

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.

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To be read in conjunction with the scope above or the attached appendix.

Certificate No: **MDSAP 832502**

Location	Registered Activities
Medivators Inc. 3150 Pollok Drive Conroe Texas 77303 USA Facility ID Number: F008421	The Design and Development, Manufacture and Distribution of Medical Devices used in Endoscopy Procedures and General Surgery including Disposable Valves and Sterile Tubing sets.
Medivators Inc. 3101 Pollok Drive Conroe Texas 77303 USA Facility ID Number: F008421	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.
Medivators Inc. 501 North Farm to Market 3083 Rd E Conroe Texas 77303 USA Facility ID Number: F008421	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.
Medivators Inc 750 Conroe Park North Conroe Texas 77303 USA Facility ID Number: F008421	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.
Medivators Inc. 3155 Conroe Park North Conroe Texas 77303 USA Facility ID Number: F008421	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.

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Page: 3 of 3

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