

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Diversatek Healthcare
102 E Keefe Ave
Milwaukee
Wisconsin
53212
USA

Facility ID Number: F000169

Holds Certificate No:

MDSAP 695018

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: 2019-05-03

Effective Date: 2025-04-06

Expiry Date: 2028-04-05



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 695018**

Registered Scope:

The design and development, manufacture, and distribution of sterile and non-sterile, active and non-active gastrointestinal system and endoscopy devices, including the following: Esophageal Dilatation Systems and their Related Accessories, Bite Blocks, Biopsy Valves, Endoscopic Foreign Body Management & Retrieval Devices, Polypectomy & Endoscopic Tissue Acquisition Devices, Endoscope Cleaning Devices, Endoscope Protection Devices, Endoscope Care Devices, and Transillumination Light Delivery Systems and Adaptors. The design and development, manufacture, and distribution of sterile and non-sterile general/surgical devices, including the following: Thoracic Catheters, Gastric Sump Tubes, Yankauer Suction Devices, Connecting Tubing and Suction Connectors, Irrigation/Aspiration Tubing Sets, Infiltration Tubing Sets, Irrigation/Bipolar Sets, and Insufflation Tubing Sets and Filters.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.