

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Diversatek Healthcare**
102 E Keefe Ave
Milwaukee
Wisconsin
53212
USA

Holds Certificate No: **FM 702306**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following 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.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2015-11-12

Latest Revision Date: 2018-10-18

Effective Date: 2016-04-06

Expiry Date: 2019-04-05

Page: 1 of 2



...making excellence a habit.™

Certificate No: **FM 702306**

Location	Registered Activities
Diversatek Healthcare 102 E Keefe Ave Milwaukee Wisconsin 53212 USA	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.
Diversatek Healthcare 9150 Commerce Center Circle #500 Highlands Ranch Colorado 80129 USA	The design and development, manufacture, servicing and distribution of active and non-active gastrointestinal system diagnostic medical devices, including the following: Reflux Monitoring Systems and Recorders, Gastrointestinal Manometry Systems and Recorders, pH and Impedance Probes and their Related Accessories, Nerve Latency Testing Systems and their Related Accessories, and Catheter, Cables, Software and Accessories for the above.

Original Registration Date: 2015-11-12

Latest Revision Date: 2018-10-18

Effective Date: 2016-04-06

Expiry Date: 2019-04-05

Page: 2 of 2

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