

# 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-11-12

Effective Date: 2019-04-06

Latest Revision Date: 2019-04-03

Expiry Date: 2022-04-05



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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.

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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.

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A Member of the BSI Group of Companies.