By Royal Charter

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 Number: 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 nonactive 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, contract 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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2015-11-12
Latest Revision Date: 2025-02-25

Effective Date: 2025-04-06
Expiry Date: 2028-04-05

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