

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Diversatek Healthcare
9150 Commerce Center Circle #500
Highlands Ranch
Colorado
80129
USA

Facility ID Number: F001854

Holds Certificate No:

MDSAP 712055

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design and development, manufacture, servicing and distribution of active and non-active gastrointestinal system diagnostic medical devices, including the following: Reflux Monitoring Systems, Gastrointestinal Manometry Systems, pH and Impedance Probes, Mucosal Integrity Testing Systems, and Related Accessories, Catheters, and associated Cables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-05-03

Effective Date: 2022-04-06

Expiry Date: 2025-04-05



BSI Group America Inc. is an MDSAP authorized auditing organization

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