bsi.

By Royal Charter

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

DUNS Number: 08-111-2563

Holds Certificate No: **MDSAP 712055**

Statement of Conformity: The company listed on this certificate has been audited to 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; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; 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 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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-05-03 Effective Date: 2019-05-03 Expiry Date: 2022-04-05

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™