



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

Facility ID Number: F001854

Holds Certificate No:

**MDSAP 712055**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

  
Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-05-03

Effective Date: 2025-04-06

Expiry Date: 2028-04-05



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

...making excellence a habit.™

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

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 712055**

## Registered Scope:

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.



Original Registration Date: 2019-05-03      Effective Date: 2025-04-06      Expiry Date: 2028-04-05

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](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.