

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Diversatek Healthcare  
102 E Keefe Ave  
Milwaukee  
Wisconsin  
53212  
USA

DUNS Number: 03-065-0113

Holds Certificate No:

**MDSAP 695018**

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

Please see scope page.

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



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 695018**

## Registered Scope:

The design and development, manufacture, and distribution of disposable sterile and nonsterile thoracic catheters, trocar catheters, gastric sump tubes, yankauer suction devices, connecting tubing, 5-in-1 connectors, irrigation/aspiration tubing, irrigation/bipolar sets, insufflation tubing sets and filters, reusable non-sterile transillumination and light delivery fiber optic cables and adaptors, disposable sterile transillumination tips, disposable non-sterile bite blocks, endoscope cleaning brushes, endoscope cleaning sponges, reusable non-sterile esophageal dilators, esophageal dilator storage cases, disposable and reusable non-sterile esophageal dilator cleaning brushes and adapters, and gastroenterology guidewires for thoracic drainage, gastric suction, aspiration and irrigation, insufflation, transillumination and light delivery devices, endoscope protection and cleaning, and esophageal dilation applications.



Original Registration Date: 2019-05-03      Effective Date: 2019-05-03

Expiry Date: 2022-04-05

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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.