

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASAHI INTECC HANOI CO., LTD.  
Thang Long Industrial Park,  
Dong Anh District,  
Hanoi,  
Vietnam

Facility ID Number: F004402

Holds Certificate No:

**MDSAP 720017**

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. 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, manufacture and distribution of Catheters for the area of cardiovascular, neurovascular, peripheral vascular and gastroenterology.  
The design, manufacture and distribution of Guidewires for the area of cardiovascular, neurovascular, peripheral vascular, gastroenterology, urology, trachea and bronchus.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-11-15

Effective Date: 2022-11-15

Expiry Date: 2025-09-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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