

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASAHI INTECC (THAILAND) CO.,LTD.
158/1 Moo 5, Bangkadi Industrial Park,
Tiwanon Road, Tambol Bangkadi,
Amphur Muang Pathumthani,
Pathumthani
12000
Thailand

Facility ID Number: F004421

Holds Certificate No:

MDSAP 718545

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 Medical Devices

Original Registration Date: 2020-05-04

Effective Date: 2023-03-25

Expiry Date: 2026-03-24



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

...making excellence a habit.™

Certificate No: **MDSAP 718545**

Registered Scope:

The design and development of Catheters for the area of Peripheral vascular.

The manufacture of Guidewire for the area of cardiovascular, peripheral vascular, neurovascular, and urology.

The manufacture of catheters for the area of cardiovascular, peripheral vascular, and neurovascular.



Original Registration Date: 2020-05-04

Effective Date: 2023-03-25

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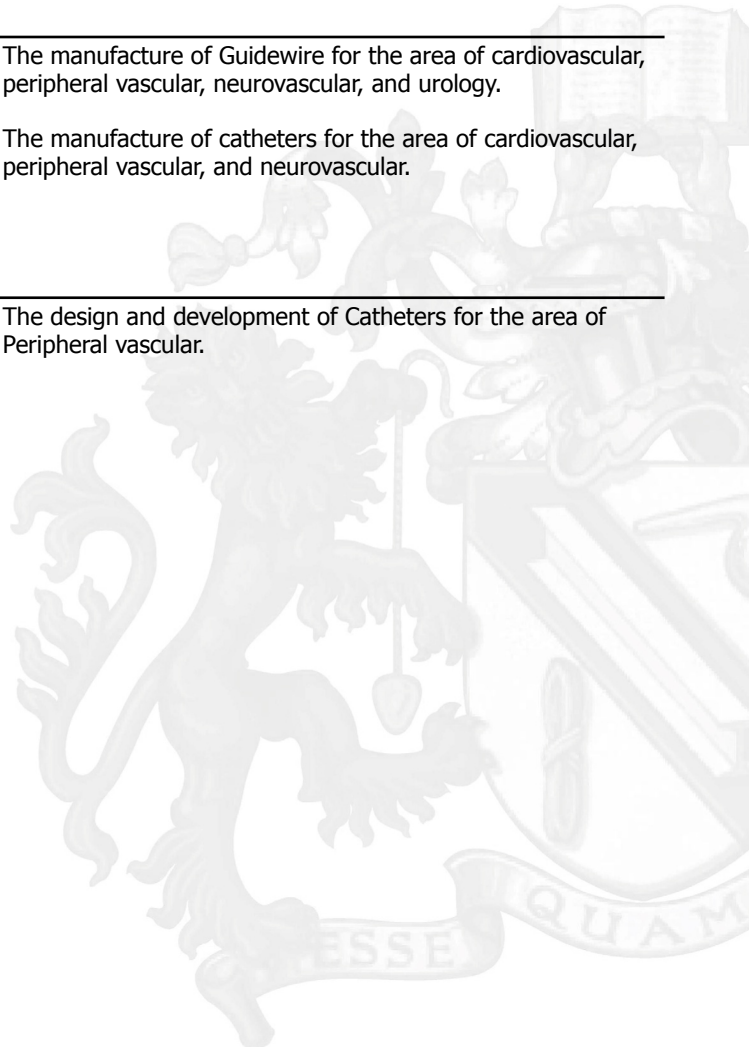
Page: 2 of 3

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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 718545**

Location	Registered Activities
ASAHI INTECC (THAILAND) CO.,LTD. N1 Factory / N2 Factory 142/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand Facility ID Number: F004421	The design and development of Catheters for the area of Peripheral vascular. The manufacture of Guidewire for the area of cardiovascular, peripheral vascular, neurovascular, and urology. The manufacture of catheters for the area of cardiovascular, peripheral vascular, and neurovascular.
ASAHI INTECC (THAILAND) CO.,LTD. 158/1 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand Facility ID Number: F004421	The manufacture of Guidewire for the area of cardiovascular, peripheral vascular, neurovascular, and urology. The manufacture of catheters for the area of cardiovascular, peripheral vascular, and neurovascular.
ASAHI INTECC (THAILAND) CO.,LTD. N3 Factory, 149 Moo 5, Bangkadi Industrial Park, Tiwanon Road, Tambol Bangkadi, Amphur Muang Pathumthani, Pathumthani 12000 Thailand Facility ID Number: F004421	The design and development of Catheters for the area of Peripheral vascular.



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