By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ASAHI INTECC CO., LTD.
3-100 Akatsuki-cho,
Seto,
Aichi
489-0071
Japan

Facility ID Number: F000506

Holds Certificate No: **MDSAP 696056**

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: 2019-03-26 Effective Date: 2023-11-08 Expiry Date: 2024-12-03

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

...making excellence a habit.™

Certificate No: **MDSAP 696056**

Registered Scope:

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

The design and manufacture of sterile endoscopic electrosurgical instruments for the area of gastroenterology.

Original Registration Date: 2019-03-26 Effective Date: 2023-11-08 Expiry Date: 2024-12-03