



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Fuji Systems Corporation  
Shirakawa Plant  
200-2 Aza-Ohira,  
Odakura, Nishigo,  
Nishi Shirakawa Gun,  
Fukushima  
961-8061  
Japan

Facility ID Number: F000190

Holds Certificate No:

**MDSAP 684811**

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: 2018-10-23

Effective Date: 2024-08-22

Expiry Date: 2027-06-02



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 684811**

## Registered Scope:

The design and development, manufacture, and distribution of catheters, drains, tubing, infusion administration set, fluid reservoir, introducer needles, filters, shunts, guidewires, clamps, non-adhesive dressing, eustachian tube prosthesis, and disposable surgical instruments for the areas of anaesthesiology, cardiovascular, ENT, gastroenterology, neurology, obstetrics & gynaecology, plastic surgery, thoracoabdominal surgery, and urology.



Original Registration Date: 2018-10-23

Effective Date: 2024-08-22

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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.

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 684811**

Location

Registered Activities

Fuji Systems Corporation  
Shirakawa Plant  
200-2 Aza-Ohira,  
Odakura, Nishigo,  
Nishi Shirakawa Gun,  
Fukushima  
961-8061  
Japan  
Facility ID Number: F000190

The design and development, manufacture, and sterilization of catheters, drains, tubing, infusion administration set, fluid reservoir, introducer needles, filters, shunts, guidewires, clamps, non-adhesive dressing, eustachian tube prosthesis, and disposable surgical instruments.

Fuji Systems Corporation  
Shin-Shirakawa Plant  
1-23 Tsukinoiri, Kayane,  
Shirakawa,  
Fukushima  
961-0004  
Japan  
Facility ID Number: F000190

The manufacture of catheters, drains, tubing, shunts, clamps, eustachian tube prosthesis, and disposable surgical instruments. The storage, and distribution of catheters, drains, tubing, infusion administration set, fluid reservoir, introducer needles, filters, shunts, guidewires, clamps, non-adhesive dressing, eustachian tube prosthesis, and disposable surgical instruments.

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