

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016


This is to certify that: Fuji Systems Corporation Shirakawa Plant 富士システムズ株式会社
200-2 Aza-Ohira, 白河工場
Odakura, Nishigo, 〒961-8061
Nishi Shirakawa Gun, 福島県
Fukushima 西白河郡
961-8061 西郷村小田倉字大平200-2
Japan

Holds Certificate No: MD 83583

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, sterilization, storage and distribution of catheters, drains, tubing, gauze, surgical microscope drape, vascular clip, plug, surgical instruments and components.
カテーテル、ドレーン、チューブ、ガーゼ、手術用顕微鏡カバー、血管クリップ、プラグ、手術用器具及び医療用部材の設計開発、製造、滅菌、保管及び出荷

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2004-06-03

Effective Date: 2024-06-03

Latest Revision Date: 2024-05-17

Expiry Date: 2027-06-02



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Location

Fuji Systems Corporation Shirakawa Plant
200-2 Aza-Ohira,
Odakura, Nishigo,
Nishi Shirakawa Gun,
Fukushima
961-8061
Japan
富士システムズ株式会社
白河工場
〒961-8061
福島県
西白河郡
西郷村小田倉字大平200-2

Registered Activities

Design, manufacture and sterilization of catheters, drains, tubing, gauze, surgical microscope drape, vascular clip, plug, surgical instruments and components.
カテーテル、ドレーン、チューブ、ガーゼ、手術用顕微鏡カバー、血管クリップ、プラグ、手術用器具及び医療用部材の設計開発、製造、滅菌

Fuji Systems Corporation
Shin-Shirakawa Plant
1-23 Tsukinoiri, Kayane,
Shirakawa,
Fukushima
961-0004
Japan
富士システムズ株式会社
新白河工場
〒961-0004
福島県
白河市
萱根月ノ入1-23

Manufacture of catheters, drains, tubing, vascular clip and Plug.
Storage and distribution of catheters, drains, tubing, gauze, surgical microscope drape, vascular clip, plug, surgical instruments and components.
カテーテル、ドレーン、チューブ、血管クリップ及びプラグの製造
カテーテル、ドレーン、チューブ、ガーゼ、手術用顕微鏡カバー、血管クリップ、プラグ、手術用器具及び医療用部材の保管および出荷

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone 045-414-3022

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