



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

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

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 Medical Devices

Original Registration Date: 2004-06-03

Latest Revision Date: 2022-07-11

Effective Date: 2021-06-03

Expiry Date: 2024-06-02

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Location	Registered Activities
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	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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