



Certificate of Registration

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

This is to certify that:

FUJIFILM SonoSite, Inc. 21919 30th Drive SE Bothell Washington 98021 USA

Holds Certificate Number:

MD 665140

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

The design, manufacture, distribution and servicing of portable medical diagnostic ultrasound equipment, hemodynamic monitoring system, laser delivery unit and accessories.

For and on behalf of BSI:

JM SI

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-12-15 Latest Revision Date: 2019-12-10





Effective Date: 2019-12-15

Expiry Date: 2022-12-14

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 665140

Location

FUJIFILM SonoSite, Inc. Administrative and Manufacturing. 21919 30th Drive SE Bothell Washington 98021 USA FUJIFILM SonoSite Inc. Administrative, Storage, Shipping, and Service. 22011 30th Drive SE Bothell Washington 98021 USA FUJIFILM Medical Co., Ltd. Import and distribution of portable medical diagnostic ultrasound equipment and accessories. FUJIFILM Nishiazabu Bldg. 26-30, Nishiazabu 2-chome Minato-ku Tokyo 106-0031 Japan Sales, distribution and service of portable medical diagnostic FUJIFILM SonoSite Australasia Pty Ltd ultrasound equipment. 114 Old Pittwater Road Brookvale New South Wales 2100 Australia FUJIFILM SonoSite BV Servicing, refurbishing and sales. Joop Geesinkweg 140 Amsterdam 1114 AB The Netherlands Warehouse and Receiving. FUJIFILM SonoSite, Inc. 18421 Bothell Everett Highway Bothell Washington 98012 USA

Original Registration Date: 2016-12-15 Latest Revision Date: 2019-12-10 Effective Date: 2019-12-15 Expiry Date: 2022-12-14

Registered Activities

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