Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

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

DUNS Number: 01-443-8860

Holds certificate No: **MDSAP 640630**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan – MHLW Ministerial Ordinance 169, Article 4 to 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-06-27 Effective Date: 2018-06-27 Expiry date: 2021-06-26

...making excellence a habit.™

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

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