bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 02429**

Issued To: **FUJIFILM SonoSite, Inc.**
21919 30th Drive SE
Bothell
Washington
98021
USA

In respect of:

The design, development and manufacture of portable diagnostic ultrasound equipment, transducers and other associated accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 September 1999** Date: **25 February 2016** Expiry Date: **22 June 2019**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 02429**
Date:	**25 February 2016**
Issued To:	**FUJIFILM SonoSite, Inc.** **21919 30th Drive SE** **Bothell** **Washington** **98021** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Molenstraat 15 2513 BH, The Hague Netherlands	**EU Representative**
FUJIFILM VisualSonics, Inc. 3080 Yonge Street Suite 6100 Toronto M4N 3N1 Canada	**Design**
GE Vingmed Ultrasound A/S Strandpromenaden 45 N3191, Horten Norway	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Sonele Inc. 46 Riviera Drive Markham Ontario L3R 5M1 Canada	**Manufacture**
Sound Technology, Inc 345 Inverness Drive S Building A, Suite 120 Englewood Colorado 80112 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02429**

Date: **25 February 2016**

Issued To: **FUJIFILM SonoSite, Inc.**
21919 30th Drive SE
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Date	Reference Number	Action
13 September 1999		Original Issue of Annex V certificate for the manufacture of portable diagnostic ultrasound equipment transducers and other associated accessories
07 December 1999		Re-issued to include design and development and replaced Annex V with Annex II
06 December 2000		Re-issued to record change of address and addition of on-site manufacture (previously sub-contracted)
30 July 2003		Re-issued certificate in new format
30 July 2004		Five years renewal
23 June 2009	7215068	Certificate renewal Addition of 'SonoSite Ltd. Europe Headquarters, Alexander House, 40A Wilbury Way, Hitchin, Herts, SG4 0AP' as the EU Representative sub-contractor
08 February 2010	7454692	Re-issue due to extension to scope to include Hemodynamic monitoring systems, and sterile optical stylets for use with catheter guidance systems. Addition of subcontractors, Pioneer Optics Company, Life Science Outsourcing, Inc. and Centurion Sterilization Services

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
07 December 2012	7919524	Reissue due to change of company name to FUJIFILM SonoSite, Inc. and change of EU Representative name to FUJIFILM SonoSite Ltd. Removal of significant subcontractors, Pioneer Optics Company, Life Science Outsourcing, Inc and Centurion Sterilization Services
21 March 2013	7970147	Replace significant subcontractors, 'FUJIFILM SonoSite Ltd., Hitchin' with 'Emergo Europe, Netherlands' as EU Representative.
05 June 2014	8111658	Certificate renewal. Addition of significant subcontractors for manufacture; GE Vingmed Ultrasound A/S and Sound Technology, Inc. Change to certificate scope to remove "hemodynamic monitoring systems, and sterile optical stylets for use with laser catheter guidance systems".
25 February 2016	8486396	Reissue to add significant subcontractors 'FUJIFILM VisualSonics, Inc., M4N 3N1, Canada', for design and 'Sonele Inc., L3R 5M1, Canada', for manufacture.