

# 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 and transducers.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1999-09-13**

Date: **2019-06-07**

Expiry Date: **2024-06-22**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 02429

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1202	Ultrasound imaging Systems and transducers	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Fujifilm Sonosite B.V. Joop Geesinkweg 140 Amsterdam 1114 AB The Netherlands	<b>EU Representative</b>
FUJIFILM VisualSonics, Inc. 3080 Yonge Street Suite 6100 Toronto M4N 3N1 Canada	<b>Design</b>
GE Vingmed Ultrasound A/S Strandpromenaden 45 N3191, Horten Norway	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Plexus Manufacturing SDN BHD Plot 87, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Penang Malaysia	<b>Manufacture</b>
Sonele Inc. 46 Riviera Drive Markham Ontario L3R 5M1 Canada	<b>Manufacture</b>
Sound Technology, Inc 401 Science Park Road State College PA 16803 USA	<b>Manufacture</b>

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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

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Page 1 of 3

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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.
02 January 2019	9659583	Reissue to change EU representative from Emergo Europe to Fujifilm Sonosite B.V.

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Date	Reference Number	Action
03 January 2019	7781688	Traceable to NB 0086.
Current	9718575	Certificate Renewal. Addition of manufacturing subcontractor Plexus Manufacturing SDN BHD. Change of subcontractor address for Sound Technology, Inc. Reduction of scope to remove associated accessories and addition of device table.