

**bsi.**

Certificate

# Full Quality Assurance

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, hemodynamic monitoring systems, and sterile optical stylets for use with laser catheter guidance systems.**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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

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Gary Fenton, Global Assurance Director

First Issued: **13 Sep 1999**

Date: **21 Mar 2013**

Expiration Date: **22 Jun 2014**

Page: 1 of 1

*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

...making excellence a habit.™



## 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>
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative

# Certificate

## History of Quality Assurance Certificate

**Certificate No: CE 02429**  
**Date: 21 Mar 2013**  
**Issued to: FUJIFILM SonoSite, Inc.**  
**Bothell**  
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**USA**

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



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Date	Reference Number	Action
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
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.