By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 72783**

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

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of Needle Guide Kits used with diagnostic ultrasound systems

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

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

Gary Fenton, Global Assurance Director

First Issued: **18 February 2003** Date: **05 June 2014** Expiry Date: **22 June 2019**

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
CIVCO Medical Instruments Co Inc 102 First Street South Kalona Iowa 52247 USA	**Manufacture**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
18 February 2003		Initial issue for the L25 Needle Guide Kit, part number P03123
05 December 2003		Up-date to include additional part numbers P03907, P03908 and P04053
30 July 2004		Certificate renewal to align with CE 02429 (Annex II) certificate five years renewal Change to scope to include generic product name Also removal of specific needle kit part numbers
23 June 2009	7389288	Certificate renewal Addition of 'SonoSite Ltd. Europe Headquarters, Alexander House, 40A Wilbury Way, Hitchin, Herts, SG4 0AP' as the EU Representative sub-contractor
07 December 2012	7919525	Reissue due to change of company name to FUJIFILM SonoSite, Inc. and change of EU Representative name to FUJIFILM SonoSite Ltd.
23 April 2013	7970147	Reissue due to change of EU Representative from 'FUJIFILM SonoSite Ltd' to 'Emergo Europe'
05 June 2014	8111661	Certificate renewal