CE 0086

Declaration of Conformity

According to EN45014

SonoSite FUJIFILM

Manufacturer's Name & Address:

FUJIFILM SonoSite, Inc.
21919 - 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized Representative's Name & Address:

Emergo Europe
Molenstraat 15
2513 BH, The Hague, The Netherlands

Declares that the CE-marked product(s):

Item	Part Number(s)	GMDN Code
SonoSite® 180™ Hand-Carried Ultrasound System	P00007	40761, 40762, 40763, 40764
SonoHeart™ Personal Hand-Carried Ultrasound Sytem	P00929	40761, 40762, 40763, 40764
SonoSite® 180™ HF Hand-Carried Ultrasound System and SonoHeart™ HF Hand-Carried Ultrasound System	P01103, P01163, P01424	40761, 40762, 40763, 40764
SonoSite® 180PLUS™, SonoHeart™ PLUS, and SonoHeart™ ELITE Hand-Carried Ultrasound System	P01576, P02030, P02031, P02462, P02463, P02464, P02521, P02522, P04247, P04248, P04249, P04250, P04251, P04252, P04253, P04254, P04255, P04256, P04257, P04258	40761, 40762, 40763, 40764
Transducer, C8/8-5	P03741	40771, 40772
Transducer, C11/7-4	P01652, P01960, P02268, P02645	40767, 40768
Transducer, C15/4-2	P00798, P01346, P01677, P02099, P02461 P02594, P03368	40767, 40768
Transducer, C60/5-2	P00005, P01150, P01385, P02098, P02115, P02133, P03367	40767, 40768
Transducer, HST/10-5	P02954, P03237, P03542	40770
Transducer, ICT/7-4	P00006, P01151, P01343, P01368, P01382, P01956, P02096, P02097, P02450	40771, 40772
Transducer, L38/10-5	P01088, P01910, P01919, P02095, P02475, P03366	40767, 40768
Transducer, L25/10-5	P04034	40767, 40768

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex II, and are Class IIa devices in accordance with Annex IX, Rule 10. EC Certificate 02429, has been issued by the British Standards Institution for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, that said products comply with the applicable requirements of:

Conformity Assessment Certificate:

CE 02429 Full Quality Assurance Certificate first issued 13 September 1999 by BSI in respect of the design, development and manufacture of portable diagnostic ultrasound equipment, transducers and other associated accessories.

Standards Applied:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 1993
- EN60601-1-2:2001

Quality Management and Quality Assurance:

- ISO 9001:2008, Quality management systems -- Requirements International Organization for Standardization
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes

April 2, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems