

# EC DECLARATION OF CONFORMITY

Manufacturer Siemens Medical Solutions USA, Inc.  
685 East Middlefield Road  
Mountain View, CA 94043 USA

Facility Jabil, Inc.  
3800 Giddings Road, Auburn Hills,  
Michigan, 48326, USA  
Transducer Facility – See page 2

EC Representative Siemens Healthcare GmbH  
Henkestr. 127, 91052 Erlangen, Germany

Type of device Diagnostic Ultrasound System

Medical device ACUSON Sequoia Diagnostic Ultrasound System

Product identification See page 2

GMDN Code/Term: 40761/ Ultrasound system, imaging, general-purpose

Classification Class IIa (according to Annex IX Council Directive 93/42/EEC)

We declare the compliance of the above medical device is in conformity with the following Directive(s):

Council Directive 93/42/EEC

The conformity of the full quality assurance system according to Annex II without Chapter II.4 is certified by:

TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 Muenchen  
Germany

The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 0123.

Directive 2011/65/EU of the European Parliament and of the Council  
Relevant Harmonized Standard: <EN 50581:2012>

This declaration of conformity is issued under the sole responsibility of Siemens Medical Solutions USA, Inc.

This declaration supersedes any declaration issued previously for the same product.

Place and date Mountain View, CA, May. 3, 2018

Name Mazi Kiani  
(Head of Quality Management)

Signature 

For conditions of guarantee and liability please refer to our General Conditions of Sale.

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**Product identification**

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<b>System</b>	<b>Labeled Part Number</b>
ACUSON Sequoia™ Diagnostic Ultrasound System	11148775

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<b>Transducer Facility</b>	<b>Transducer Name</b>	<b>Labeled PN</b>
Siemens Healthineers Ltd. 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro, Nam-gu Pohang-si Gyeongsangbuk-do, Republic of Korea	5C1	11291794
	5V1	11291796
	DAX	10787116
	10L4	10787114
	14L5	11254090
	18L6	10787113
	9C3	10787112
	4V1	11014576
	8V3	11014578
Sound Technology, Inc. 401 North Science Park Road, State College Pennsylvania, 16803, USA	CW2	10789380
Konica Minolta, Inc. 1 Sakura-machi, Hino-shi Tokyo, 191-8511, Japan	9EC4	10787117

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