

# EC DECLARATION OF CONFORMITY

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

Facility Siemens Medical Solutions USA, Inc.  
2500 Millbrook Drive, Suite B  
Buffalo Grove, IL 60089, 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 S1000™ 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, Jan. 1, 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**

<b>System</b>	<b>Labeled PN</b>
ACUSON S1000™ Diagnostic Ultrasound system	10441701

<b>Transducer Facility</b>	<b>Transducer Name</b>	<b>Labeled PN</b>
Konica Minolta Technoproducts Co., Ltd. 1 Sakura-machi, Hino-shi Tokyo, 191-8511, Japan	7CF2	10043226
	7CF1	10658925
	9EVF4	10041223
	MC9-4	10349999

Siemens Healthineers Ltd. 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro Nam-gu, Pohang-si, Gyeongsangbuk-do Republic of Korea	14L5	10789396
	9L4	10789393
	4V1	08252072
	4C1	08258525
	4P1	10789398
	V5Ms	11013704
	EC9-4	10041225
	4V1c	07695724
	14L5 SP	10041226
	18L6 HD	10789400
	12L4	10786035
	6C2	08248186
	10V4	08266709
	8V3	10789382
AcuNav 8F	10135936	
AcuNav 10F	08255790	

Sound Technology, Inc. 401 North Science Park Road State College, Pennsylvania, 16803, USA	CW2	10789380
	CW5	10789381
	EV-8C4	11013910

Oldelft B.V. Elektronicaweg 10 2628 XG Delft, Netherlands	V7M	10855905
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