

# 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  
Henkestrasse 127, 91052 Erlangen, Germany

Type of device Diagnostic Ultrasound System

Medical device ACUSON SC2000™ Diagnostic Ultrasound System

Product identification See page 2

GMDN Code/Term: 40763/ Ultrasound system, imaging, cardiovascular

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, July 12, 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

### System

ACUSON SC2000™ Diagnostic Ultrasound System

### Labeled Part Number

10433816

### Workplace

ACUSON SC2000™ Workplace

### Labeled PN

10433921

Siemens Medical Solutions USA, Inc.  
2501 North Barrington Road  
Hoffman Estates, IL 60192, USA

### Transducer Facility

### Transducer Name

### Labeled PN

Siemens Healthcare Ltd.  
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Pohang-si, Gyeongsangbuk-do  
Republic of Korea

4Z1c

10789391

4V1c

07695724

V5Ms

11013704

8V3

10789382

6C1 HD

10135941

9L4

10789393

10V4

08266709

AcuNav 8F

10135936

AcuNav 10F

08255790

AcuNav V

10043260

Z6Ms

10436113

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