

# EU DECLARATION OF CONFORMITY

## Manufacturer

Name: Siemens Medical Solutions USA, Inc.  
Address: 22010 S.E. 51st Street  
Issaquah, WA 98029, USA

Single Registration  
Number (SRN): US-MF-000012284

## Authorized Representative:

Name: Siemens Healthcare GmbH  
Address: Henkestr. 127  
91052 Erlangen  
Germany

SRN Authorized  
Representative: DE-AR-000011241

## Facility

Name: Siemens Medical Solutions USA, Inc.  
Address: 22010 S.E. 51st Street  
Issaquah, WA 98029, USA  
Transducer Facility - See next pages

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**Product Identification**      see next page

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We declare that the above medical devices are in conformity with the following legislation(s):

**Medical Device Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices**  
The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified  
body:

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 IX and Article 52 to the  
above regulation is: 0123  
Certificate number of issued certificate: G10 022775 0012  
Reference to Common Specifications: /

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**RoHS Directive 2011/65/EU (as amended by 2015/863/EU) of the European Parliament and of the Council of 8 June 2011**  
**on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

Relevant Harmonized Standard: EN IEC63000:2018

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

Place Issaquah, WA

Signature  
Name



Jim Dabbs  
Head of Quality Management, PRRC

Date: 13 APRIL 2023

For conditions of warranty and liability please refer to the General Conditions of Sale.

Document number: 11509609-QMS-120-08

**Product identification**

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
ACUSON SEQUOIA Diagnostic Ultrasound System	11148775	0405686900844VX	04056869173566	40761	General-purpose ultrasound imaging system	Z11040101	GENERAL PURPOSE ULTRASOUND SCANNERS	Ila / 10

Transducer Facility:

Siemens Healthineers Ltd.

2nd & 3rd Venture Building

Pohang Technopark, 394, Jigok-ro, Nam-gu, Pohang-si

Gyeongsangbuk-do, Republic of Korea

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
5C1 Transducer	11291794	0405686900843VV	04056869061870	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
5V1 Transducer	11291796	0405686900843VV	04056869062013	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
DAX Transducer	10787116	0405686900843VV	04056869051970	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
10L4 Transducer	10787114	0405686900843VV	04056869051994	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
14L5 Transducer	11254090	0405686900843VV	04056869052021	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>18L6 Transducer</b>	11575184	0405686900843VV	04056869284576	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>9C3 Transducer</b>	11575182	0405686900843VV	04056869284569	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>4V1 Transducer</b>	11014576	0405686900843VV	04056869052045	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>8V3 Transducer</b>	11014578	0405686900843VV	04056869052069	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>10V4 Transducer</b>	11014579	0405686900843VV	04056869052076	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>15L4 Transducer</b>	11289427	0405686900843VV	04056869287669	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>9C2 Transducer</b>	11503103	0405686900843VV	04056869266275	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>10EV3 Transducer</b>	11502928	0405686900843VV	04056869266268	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

TransducerWorks, LLC  
2821 Earlstown Rd.  
Centre Hall, PA, 16828 USA

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>CW2 Transducer</b>	10789380	0405686900843VV	04056869003795	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>CW5 Transducer</b>	10789381	0405686900843VV	04056869003801	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

Konica Minolta Technoproducts Co., Ltd  
2-2-1 Hirosedai, Sayama-shi,  
Saitama, 350-1328, Japan

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>9EC4 Transducer</b>	10787117	0405686900843VV	04056869062020	40771	Rectal/vaginal ultrasound imaging transducer	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>9VE4 Transducer</b>	11289564	0405686900843VV	04056869243566	40771	Rectal/vaginal ultrasound imaging transducer	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
<b>7VC2 Transducer</b>	11289565	0405686900843VV	04056869274959	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

HUMANSCAN CO., LTD.

15, Emtibeuibuk-ro 137beon-gil, Siheung-si,  
Gyeonggi-do, 15119, Republic of Korea

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>7L2 Transducer</b>	11289562	0405686900843VV	04056869243573	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

VERMON

180, rue du Général Renault BP  
3813 FR-37038 TOURS CEDEX, France

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>18H6 Transducer</b>	11289567	0405686900843VV	04056869245386	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

GE Medical Systems (China) Co., Ltd.

No. 19, Changjiang Road, Wuxi National Hi-Tech Dev. Zone  
214028 Jiangsu, China

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
<b>11M3 Transducer</b>	11289561	0405686900843VV	04056869243597	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10