

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

Facilities

Name: **Siemens Healthcare s.r.o.**
Address: Panattoni Park Kosice Airport ul. Andreja Kvasa 5 040 17, Kosice-Barca, Slovakia

Transducer Facility - See next pages

Product Identification see next page

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: /

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

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

Place and date Issaquah, WA, Oct 20, 2023

Signature



Name

Jim Dabbs
Head of Quality Management, PRRC

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

Product identification

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
ACUSON Maple Diagnostic Ultrasound System	11711750	0405686900844VX	04056869995809	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
8V4 Transducer	11284847	0405686900843VV	04056869051901	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10
16L4 Transducer	11284846	0405686900843VV	04056869051918	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10
5C1a Transducer	11711957	0405686900843VV	04056869990408	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10
7C2 Transducer	11268277	0405686900843VV	04056869051956	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10
10MC3 Transducer	11268679	0405686900843VV	04056869059167	40771	Rectal/vaginal ultrasound imaging transducer	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
5VT Transducer	11370949	0405686900843VV	04056869238272	37891	Osophageal ultrasound imaging transducer, reusable	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / / 10
14L4a Transducer	11711446	0405686900843VV	04056869990392	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10
P4-2 Transducer	10136143	0405686900843VV	04056869005522	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10

Transducer Facility:

TransducerWorks, LLC

2821 Earlystown 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
CW2 Transducer	10789380	0405686900843VV	04056869003795	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / /10
CW5 Transducer	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
11M3 Transducer	11284923	0405686900843VV	04056869059204	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
L10-5v Transducer	11319682	0405686900843VV	04056869055466	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / / 10
C5-2v Transducer	11711157	0405686900843VV	04056869986715	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / / 10

Transducer Facility:**NIHON DEMPA KOGYO CO., LTD.**

1275-2, Kamihirose, Sayama-City,
Saitama 350-1321, Japan

Product/Trade Name	Model	Basic UDI-DI	UDI-DI	GMDN Code	GMDN Term	CND Code	CND Term	Risk Class / Rule
9VC2 Transducer	11575443	0405686900843VV	04056869962771	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
9VE4 Transducer	11575444	0405686900843VV	04056869962788	40771	Rectal/vaginal ultrasound imaging transducer	Z1104018001	ULTRASOUND SCANNERS – HARDWARE	Ila / / 10