

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 Healthineers Ltd.
Address: 2nd ~ 3rd Floor, 143, Sunhwa-ro, Jungwon-gu, Seongnam-Si,
Gyeonggi-Do, REPUBLIC OF KOREA
Name: Siemens Healthcare s.r.o.
Address: Panattoni Park Kosice Airport, ul. Andreja Kvasa 5
04017 Kosice-Barca, Slovakia
Transducer Facility - See next pages

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: /

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 March 3, 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 P500 Diagnostic Ultrasound System	10785577	0405686900844VX	04056869002743	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
P4-2 Transducer	10136143	0405686900843VV	04056869005522	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
P8-4 Transducer	11014543	0405686900843VV	04056869050782	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
CH5-2 Transducer	10136141	0405686900843VV	04056869027241	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
VF10-5 Transducer	10136142	0405686900843VV	04056869005515	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
VF13-5 Transducer	10789372	0405686900843VV	04056869005591	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
VF16-5 Transducer	11014552	0405686900843VV	04056869050799	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
EC9-4 Transducer	10136144	0405686900843VV	04056869005539	40771	Rectal/vaginal ultrasound imaging transducer	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
5VT Transducer	11370949	0405686900843VV	04056869238272	37891	Esophageal ultrasound imaging transducer, reusable	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10
ACUSON AcuNav 8F Diagnostic Ultrasound Catheter	10135936	0405686901986WT	04056869001029	42584	Intracardiac ultrasound imaging catheter, steerable, single-use	C0104010102	CARDIAC AND INTRACORONARIC CATHETERS, ULTRASOUND	III / 7
ACUSON AcuNav 10F Diagnostic Ultrasound Catheter	08255790	0405686901986WT	04056869001012	42584	Intracardiac ultrasound imaging catheter, steerable, single-use	C0104010102	CARDIAC AND INTRACORONARIC CATHETERS, ULTRASOUND	III / 7

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
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
18H5 Transducer	11284924	0405686900843VV	04056869059211	40768	Extracorporeal ultrasound imaging transducer, hand-held	Z1104018001	ULTRASOUND SCANNERS - HARDWARE	Ila / 10