

EC DECLARATION OF CONFORMITY

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

Facility Siemens Healthineers Ltd.
2nd~3rd Floor, 143, Sunhwan-ro, Jungwon-gu
Seongnam-si, Gyeonggi-do, Republic of Korea
Transducer Facility – See page 2

EC Representative Siemens Healthcare GmbH
Henkestr. 127, 91052 Erlangen, Germany

Type of device Diagnostic Ultrasound System

Medical device ACUSON NX2 Elite™ 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.

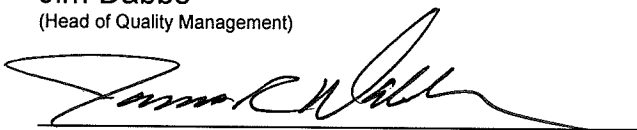
Directive 2011/65/EU (as amended by 2015/863/EU) of the European Parliament and of the Council Relevant Harmonized Standard: <EN IEC 63000: 2018>

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

Place and date Issaquah, WA, March 21, 2022

Name Jim Dabbs
(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	Labeled PN
ACUSON NX2 Elite Diagnostic Ultrasound system	11284500

Transducer Facility	Transducer Name	Labeled PN
Siemens Healthineers Ltd. 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro Nam-gu, Pohang-si, Gyeongsangbuk-do Republic of Korea	CH5-2	10789386
	VF10-5	10789387
	EC9-4	10789383
	P4-2	10789385
	10MC3	11284842
Sound Technology, Inc. 401 North Science Park Road, State College Pennsylvania, 16803, USA	C8F3	10786652
TransducerWorks, LLC 2821 Earlstown Rd. Centre Hall, PA 16828, USA	CW2	10789380
	CW5	10789381
Humanscan Co., Ltd. 15, Emtibeuibuk-ro 137beon-gil, Siheung-si, Gyeonggi-do, 15119, Republic of Korea	C5-2v	11284925
	L10-5v	11284926

Attachment to EC DECLARATION OF CONFORMITY of Council Directive 93/42/EEC

Revision Data

Revision	Author	Approval Date	Change Description
01~03	See SAP	See SAP	See SAP
04	See SAP	7/20/2021	RoHS Directive updated to Directive 2011/65/EU (as amended by 2015/863/EU)
05	Emily Woo	3/21/2022	Facility changed from STI to TW and there is no change in the transducer specification.