

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 Redwood™ 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 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 as of May 11, 2020.

Place Issaquah, WA

Name Christine Dunn
(Head of Quality Management)

Signature and date

For conditions of guarantee and liability please refer to our General Conditions of Sale.

Product identification

System	Labeled PN
ACUSON Redwood Diagnostic Ultrasound system	11503314

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	4V1	11014576
	5V1	11291796
	8V3	11014578
	10V4	11014579
	10L4	10787114
	14L5	11254090
	18L6	10787113
	5C1	11291794
	9C3	10787112
	V5Ms	11013704
Sound Technology, Inc. 401 North Science Park Road, State Col- lege Pennsylvania, 16803, USA	CW2	10789380
	CW5	10789381
KONICA MINOLTA TECHNOPRODUCTS CO., LTD. 2-2-1 Hirosedai, Sayama-shi, Saitama, 350-1328, Japan	9EC4	10787117