

EC DECLARATION OF CONFORMITY

Manufacturer Siemens Medical Solutions USA, Inc.
685 East Middlefield Road
Mountain View, CA 94043 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 Juniper Diagnostic Ultrasound System

Product identification See page 2-3

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.

Place and date Mountain View, CA, Feb. 8, 2018

Name Mazi Kiani
(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 Part Number
ACUSON Juniper™ Diagnostic Ultrasound System	11335791

Transducer Facility	Transducer Name	Pricebook PN Labeled PN
Siemens Healthineers Ltd. 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro, Nam-gu Pohang-si Gyeongsangbuk-do, Republic of Korea	5P1	11335890 11014154
	8V4	11335891 11284847
	10V4	11335892 11319697
	11L4	11335914 11284844
	12L3	11335918 11268279
	16L4	11335921 11284846
	5C1	11335900 11268278
	7C2	11335902 11268277
	10MC3	11335904 11268679

Product identification

Transducer Facility	Transducer Name	Pricebook PN Labeled PN
Sound Technology, Inc. 401 North Science Park Road, State College Pennsylvania, 16803, USA	CW2	11235559 10789380
	CW5	11235560 10789381
	8VC3	11335896 11284921
	9VE3	11335897 11284922
Konica Minolta Technoproducts Co., Ltd. 1 Sakura-machi, Hino-shi Tokyo, 191-8511, Japan	11M3	11335893 11284923
	9MC3,	11335910 11284920
HumanScan Co., LTD Room 301~303, 319~320 Sihwa APT Factory, Jiwon-ro 107 Danwon-gu, Ansan-si, Gyeonggi-do Republic of Korea	18H5	
		11335925 11284924