SIEMENS

EC DECLARATION OF CONFORMITY

Manufacturer

Siemens Medical Solutions USA, Inc.

685 East Middlefield Road

Mountain View, CA 94043 USA

Facility

Siemens Ltd. Seoul

2nd~3rd Floor, 143, Sunhwan-ro, Jungwon-gu Seongnam-si, Gyeonggi-do, Republic of Korea

Transducer Facility - See page 2

EC Representative

Siemens AG Medical Solutions

Henkestrasse 127, 91052 Erlangen, Germany

Type of device

Diagnostic Ultrasound System

Medical device

ACUSON P500™ ultrasound system

Product identification

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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, April 9, 2015

Name

Karen Smith

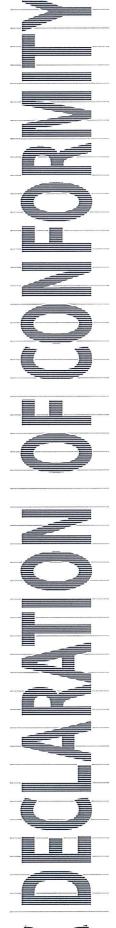
(Head of Quality Management)

Signature

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

QMS 11015153 017 01

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Product identification

System	
ACUSON P500™	Ultrasound System

Labeled Part Number 10785577

Transducer Facility	Name	Pricebook PN	Labeled PN
Siemens Ltd. Seoul 2nd & 3rd Venture Building Pohang Technopark, 394, Jigok-ro Nam-gu, Pohang-si Gyeongsangbuk-do, Republic of Korea	P4-2	11015185 (KOR)10785547	10136143 (KOR)11015393
	CH5-2	11015184 (KOR)10785545	10136141 (KOR)11015392
	VF10-5	10146142 (KOR)10785551	10136142 (KOR)11015395
	VF13-5	11015188 (KOR) 11014625	10789372 (KOR)11015396
	EC9-4	10785548 (KOR)10785549	10136144 (KOR)11015394