

## EC DECLARATION OF CONFORMITY

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

Facility Siemens Ltd. Seoul  
2<sup>nd</sup>~3<sup>rd</sup> 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 See page 2

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		Labeled Part Number	
ACUSON P500™ Ultrasound System		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