Declaration of Conformity

For the following

Product :	Diagnostic Ultrasound Apparatus
Model(s) :	MySono U6
Transducer(s):	3D4-9, 3DC2-6, C2-5, C2-8, EVN4-9, LN5-12, CF4-9, SP3-8, PN2-4, DP2B
Classfication:	IIa
Document Revision	08

Date of affixing CE marking: 15 Dec, 2011

We hereby declare, that the product above is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, is subject to the procedures set out in Annex II (excluding section 4) of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of TÜV SÜD PRODUCT SERVICE GMBH (Notified Body No.: 0123). All supporting documentation is retained under the premises of the manufacturer.

EN 980: 2008	EN 1041:2008
EN ISO 13485:2012	EN ISO 10993-1:2009
EN ISO 14971:2012	EN 60601-1:2006
EN 60601-1-2:2007	EN 60601-2-37:2008
EN 60601-1-6: 2010	EN 62366:2008
EN 62304:2006	

The Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 50581:2012.

Manufacturer:
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21 January, 2015
(Place and date of issue)

Gi Ho Kang/Regulatory Affairs Director
(Name and signature of authorized person)

EC REP **Representative in the EU:**
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Digitally signed by Bolocan Vladimir
Date: 2019.10.18 08:54:08 EEST
Reason: MoldSign Signature
Location: Moldova

Note : It is not the address of Samsung Service Centre. For the address or the phone number of Samsung Service Centre, see the warranty card or contact the retailer where you purchased your product