



Declaration of Conformity

For the following

Product : Diagnostic Ultrasound Apparatus
Model(s) : EKO 7
Transducer(s): C2-6IC, CF4-9, EV4-9/10ED, CA1-7A, L3-8, L5-13IS, P1-4, P2-4BA, P3-8CA, PE2-4, LA3-16A, MMPT3-7, CW4.0, DP2B
Classification: IIa
Document Revision 19

Date of affixing CE marking: 2010-02-25

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, Address: Ridlerstraße 65, 80339 München Germany). 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/A1:2013
EN 60601-1-2:2007	EN 60601-2-18:1996/A1:2000
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:

SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu,
Seoul, Korea

2016-09-30

(Place and date of issue)

Dongwook Shin/Regulatory Affairs Manager

(Name and signature of authorized person)



Representative in the EU:

SAMSUNG ELECTRONICS (UK) LTD.
Blackbushe Business Park
Saxony Way, Yateley, Hampshire
GU46 6GG, UK

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.



APPENDIX TO THE DECLARATION OF CONFORMITY dated 2016-09-30

Product Description	Manufacturer
EKO 7	SAMSUNG MEDISON CO., LTD.
Probe	
C2-6IC	SAMSUNG MEDISON CO., LTD.
CF4-9	SAMSUNG MEDISON CO., LTD.
EV4-9/10ED	SAMSUNG MEDISON CO., LTD.
CA1-7A	SAMSUNG MEDISON CO., LTD.
L3-8	SAMSUNG MEDISON CO., LTD.
L5-13IS	SAMSUNG MEDISON CO., LTD.
P1-4	SAMSUNG MEDISON CO., LTD.
P2-4BA	SAMSUNG MEDISON CO., LTD.
P3-8CA	SAMSUNG MEDISON CO., LTD.
PE2-4	SAMSUNG MEDISON CO., LTD.
LA3-16A	SAMSUNG MEDISON CO., LTD.
MMPT3-7	SAMSUNG MEDISON CO., LTD.
CW4.0	SAMSUNG MEDISON CO., LTD.
DP2B	SAMSUNG MEDISON CO., LTD.
SW Option	
DICOM	SAMSUNG MEDISON CO., LTD.
Spatial Compound	SAMSUNG MEDISON CO., LTD.
Dynamic MR+	SAMSUNG MEDISON CO., LTD.
AutoIMT	SAMSUNG MEDISON CO., LTD.
Panoramic	SAMSUNG MEDISON CO., LTD.
Stressecho	SAMSUNG MEDISON CO., LTD.
Strain	SAMSUNG MEDISON CO., LTD.
OB/GYN/Abdomen Measurement	SAMSUNG MEDISON CO., LTD.
ADVR	SAMSUNG MEDISON CO., LTD.
Options	
ECG module (ECG-USB1)	Norav Medical Ltd.
ECG cable (C3-C-E-ODU)	Richter Medizintechnik
Foot Switch (HY-102)	SAMSUNG MEDISON CO., LTD.