



Declaration of Conformity

For the following

Product : Diagnostic Ultrasound Apparatus
Model(s) : HS30
Transducer(s): LN5-12, L5-12/50, CF4-9, C2-5, C2-8, PN2-4, EVN4-9, ER4-9, DP2B
Classification: Ila
Document Revision 3

Date of affixing CE marking: 2018-09-06

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 ISO15223-1:2016	EN 1041:2008
EN ISO 13485:2016	EN ISO 10993-1:2009
EN ISO 14971:2012	EN 60601-1:2006/A1:2013
EN 60601-1-2:2015	EN 60601-2-37:2008/A11:2011/A1:2015
EN 60601-1-6:2010/A1:2015	EN 62366:2008/A1:2015
EN 62304:2006	EN 301 489-1:2017
EN 301-489-17:2017	

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.

The manufacturer is exclusively responsible for the declaration of conformity.



Manufacturer:

SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108,
REPUBLIC OF KOREA
2019-03-28

(Place and date of issue)

Donghwan Kim /Regulatory Affairs Manager

(Name and signature of authorized person)



Representative in the EU:

Samsung Electronics GmbH
Am Kronberger Hang 6,
65824 Schwalbach am Taunus
GERMANY

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 2019-03-28

Product Description	Manufacturer
HS30	SAMSUNG MEDISON CO., LTD.
Probe & Biopsy	
LN5-12	SAMSUNG MEDISON CO., LTD.
L5-12/50	SAMSUNG MEDISON CO., LTD.
CF4-9	SAMSUNG MEDISON CO., LTD.
C2-5	SAMSUNG MEDISON CO., LTD.
C2-8	SAMSUNG MEDISON CO., LTD.
PN2-4	SAMSUNG MEDISON CO., LTD.
EVN4-9	SAMSUNG MEDISON CO., LTD.
ER4-9	SAMSUNG MEDISON CO., LTD.
DP2B	SAMSUNG MEDISON CO., LTD.
BP-KIT-040 [BP-KIT-040-NG]	PROTEK medical Products, Inc.
BP-KIT-047 [BP-KIT-047-NG]	PROTEK medical Products, Inc.
BP-KIT-045 [BP-KIT-045-NG]	PROTEK medical Products, Inc.
BP-KIT-035 [BP-KIT-035-NG]	PROTEK medical Products, Inc.
BP-KIT-061	CIVCO Medical Instruments Co., Inc.
BP-KIT-024	PROTEK medical Products, Inc.
SW Option	
DICOM	SAMSUNG MEDISON CO., LTD.
EzExam+	SAMSUNG MEDISON CO., LTD.
MultiVision	SAMSUNG MEDISON CO., LTD.
CW Function	SAMSUNG MEDISON CO., LTD.
Cardiac Measurement	SAMSUNG MEDISON CO., LTD.
Strain+	SAMSUNG MEDISON CO., LTD.
EzAssist	SAMSUNG MEDISON CO., LTD.
NeedleMate+	SAMSUNG MEDISON CO., LTD.
Mobile Export	SAMSUNG MEDISON CO., LTD.
Auto IMT+	SAMSUNG MEDISON CO., LTD.
ElastoScan	SAMSUNG MEDISON CO., LTD.
Panoramic	SAMSUNG MEDISON CO., LTD.
Freehand 3D	SAMSUNG MEDISON CO., LTD.
Options	
ECG Module (ECG-USB1)	Norav Medical Ltd.
Foot Switch (FSU-3000 SM)	Whanam Electronics Co., Ltd.
Gel warmer	JCWell