



Declaration of Conformity

For the following

Product : Diagnostic Ultrasound Apparatus
Model(s) : HS50
Transducer(s): LA3-14AD, LA3-16A, CA1-7AD, CA2-9AD, CA2-6BM, CF4-9, ER4-9, PA3-8B, PE2-4, CV1-8AD, V5-9, CW6.0, DP2B
Classification: IIa
Document Revision 0

Date of affixing CE marking: 2016-10-25

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 60601-2-37:2008
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

2016-10-25

(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 2016-10-25

Product Description	Manufacturer
HS50	SAMSUNG MEDISON CO., LTD.
Probe & Biopsy	
LA3-14AD	SAMSUNG MEDISON CO., LTD.
LA3-16A	SAMSUNG MEDISON CO., LTD.
CA1-7AD	SAMSUNG MEDISON CO., LTD.
CA2-9AD	SAMSUNG MEDISON CO., LTD.
CA2-6BM	SAMSUNG MEDISON CO., LTD.
CF4-9	SAMSUNG MEDISON CO., LTD.
ER4-9	SAMSUNG MEDISON CO., LTD.
PA3-8B	SAMSUNG MEDISON CO., LTD.
PE2-4	SAMSUNG MEDISON CO., LTD.
CV1-8AD	SAMSUNG MEDISON CO., LTD.
V5-9	SAMSUNG MEDISON CO., LTD.
CW6.0	SAMSUNG MEDISON CO., LTD.
DP2B	SAMSUNG MEDISON CO., LTD.
BP-KIT-029	GE Healthcare Austria GmbH & Co OG
BP-KIT-024	PROTEK medical Products, Inc.
BP-KIT-043	CIVCO Medical Instruments Co., Inc.
BP-KIT-053 [BP-KIT-053-NG]	PROTEK medical Products, Inc.
BP-KIT-054 [BP-KIT-054-NG]	PROTEK medical Products, Inc.
BP-KIT-055 [BP-KIT-055-NG]	PROTEK medical Products, Inc.
BP-KIT-058 [BP-KIT-058-NG]	PROTEK medical Products, Inc.
BP-KIT-059 [BP-KIT-059-NG]	PROTEK medical Products, Inc.
BP-KIT-060	CIVCO Medical Instruments Co., Inc.
BP-KIT-061	CIVCO Medical Instruments Co., Inc.
BP-KIT-065	CIVCO Medical Instruments Co., Inc.
BP-KIT-066	CIVCO Medical Instruments Co., Inc.
BP-KIT-068 [BP-KIT-068-NG]	PROTEK medical Products, Inc.
BP-KIT-069	CIVCO Medical Instruments Co., Inc.
SW Option	
4D	SAMSUNG MEDISON CO., LTD.
3DXI™	SAMSUNG MEDISON CO., LTD.
DICOM	SAMSUNG MEDISON CO., LTD.
EzExam+	SAMSUNG MEDISON CO., LTD.
MultiVision	SAMSUNG MEDISON CO., LTD.
5D NT	SAMSUNG MEDISON CO., LTD.
CW Function	SAMSUNG MEDISON CO., LTD.
Cardiac Measurement	SAMSUNG MEDISON CO., LTD.
Auto IMT+	SAMSUNG MEDISON CO., LTD.



Product Description	Manufacturer
ElastoScan	SAMSUNG MEDISON CO., LTD.
Panoramic	SAMSUNG MEDISON CO., LTD.
XI STIC	SAMSUNG MEDISON CO., LTD.
SEE Stream (RU region only)	SAMSUNG MEDISON CO., LTD.
Needle Mate+	SAMSUNG MEDISON CO., LTD.
Realistic Vue	SAMSUNG MEDISON CO., LTD.
Mobile Export	SAMSUNG MEDISON CO., LTD.
5D Follicle	SAMSUNG MEDISON CO., LTD.
Options	
ECG Module (ECG-USB1)	Norav Medical Ltd.
Foot Switch (FSU-3000 SM)	Whanam Electronics Co., Ltd.
Gel warmer	JCWell