

EU Declaration of Conformity

For the following

Product name : Diagnostic Ultrasound Apparatus
Model(s) name : HS30
Transducer : LN5-12, L5-12/50, CF4-9 C2-5, C2-8, PN2-4 , EVN4-9 ER4-9, DP2B ,
 SP3-8, VN4-8, EV2-10A, CA2-6BM
Risk Class : IIa
Basic UDI-DI : 880972578USS001X6
Document Revision: 1

We hereby declare, that the product above is in conformity with Regulation (EU) 2017/745, is subject to the procedures set out in Annex IX(Chapter I, III & Chapter II.4) of Regulation (EU) 2017/745 under the supervision of TUV SUD (Notified Body No.: 0123).

EN ISO 15223-1:2016	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	IEC 62366-1:2015
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.

All supporting documentation is retained under the premises of the manufacturer. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:

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

2021-04-28

(Place and date of issue)

Donghwan Kim /Regulatory Affairs Manager

(Name and signature of authorized person)

**Authorised Representative:**

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 2021-04-28

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.
SP3-8	SAMSUNG MEDISON CO., LTD.
VN4-8	SAMSUNG MEDISON CO., LTD.
EV2-10A	SAMSUNG MEDISON CO., LTD.
CA2-6BM	SAMSUNG MEDISON CO., LTD.
BP-KIT-040	PROTEK medical Products, Inc.
BP-KIT-047	PROTEK medical Products, Inc.
BP-KIT-045	PROTEK medical Products, Inc.
BP-KIT-035	PROTEK medical Products, Inc.
BP-KIT-061	CIVCO Medical Instruments Co., Inc.
BP-KIT-024	PROTEK medical Products, Inc.
BP-KIT-049	PROTEK medical Products, Inc.
BP-KIT-086	PROTEK medical Products, Inc.
BP-KIT-085	PROTEK medical Products, Inc.
SW Option	
DICOM	SAMSUNG MEDISON CO., LTD.

Product Description	Manufacturer
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.
4D	SAMSUNG MEDISON CO., LTD.
XI STIC	SAMSUNG MEDISON CO., LTD.
3D XI	SAMSUNG MEDISON CO., LTD.
System Activation	SAMSUNG MEDISON CO., LTD.
LaborAssist	SAMSUNG MEDISON CO., LTD.
2D NT	SAMSUNG MEDISON CO., LTD.
Windows 10	SAMSUNG MEDISON CO., LTD.
Options	
ECG Module (ECG-USB1)	Norav Medical Ltd.
Foot Switch (FSU-3000 SM)	Whanam Electronics Co., Ltd.
Gel warmer	JCWell