

EU Declaration of Conformity

For the following

Product name : Diagnostic Ultrasound Apparatus
Model(s) name : HM70A
Transducer : C2-6, CF4-9, SC1-6, CA1-7AD, CA2-9AD, EVN4-9, L4-7, L5-13, L7-16, LS3-14B, LA3-16AD, LS6-15, PE2-4, P3-8, P4-12, PA1-5A, VN4-8, V5-9, CV1-8AD, CW2.0, CW4.0, DP2B, MMPT3-7
Risk Class : IIa
Basic UDI-DI : 880972578USS001X6
Document Revision: 0

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 13485:2016	EN ISO 10993-1:2009
EN ISO 14971:2012	EN 60601-1:2006/A1:2013
EN 60601-1-2:2015	EN 60601-2-18:2015
EN 60601-2-37:2008/A11:2011/A1:2015	EN 60601-1-6:2010/A1:2013
EN 62366:2008	EN 62304:2006
EN 1041:2008	EN ISO 15223-1:2016

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

2021-04-01

(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 2021-04-01

Product Description	Manufacturer
UGEO HM70A	SAMSUNG MEDISON CO., LTD.
HM70A	SAMSUNG MEDISON CO., LTD.
Probe & Biopsy	
C2-6	SAMSUNG MEDISON CO., LTD.
CF4-9	SAMSUNG MEDISON CO., LTD.
SC1-6	SAMSUNG MEDISON CO., LTD.
CA1-7AD	SAMSUNG MEDISON CO., LTD.
CA2-9AD	SAMSUNG MEDISON CO., LTD.
EVN4-9	SAMSUNG MEDISON CO., LTD.
L4-7	SAMSUNG MEDISON CO., LTD.
L5-13	SAMSUNG MEDISON CO., LTD.
L7-16	SAMSUNG MEDISON CO., LTD.
LA3-16AD	SAMSUNG MEDISON CO., LTD.
LS6-15	SAMSUNG MEDISON CO., LTD.
LS3-14B	SAMSUNG MEDISON CO., LTD.
PE2-4	SAMSUNG MEDISON CO., LTD.
P3-8	SAMSUNG MEDISON CO., LTD.
P4-12	SAMSUNG MEDISON CO., LTD.
PA1-5A	SAMSUNG MEDISON CO., LTD.
VN4-8	SAMSUNG MEDISON CO., LTD.
V5-9	SAMSUNG MEDISON CO., LTD.
CV1-8AD	SAMSUNG MEDISON CO., LTD.
CW2.0	SAMSUNG MEDISON CO., LTD.
CW4.0	SAMSUNG MEDISON CO., LTD.
DP2B	SAMSUNG MEDISON CO., LTD.
MMPT3-7	SAMSUNG MEDISON CO., LTD.
BP-KIT-009	CIVCO Medical Instruments Co., Inc.

Product Description	Manufacturer
BP-KIT-012	CIVCO Medical Instruments Co., Inc.
BP-KIT-043	CIVCO Medical Instruments Co., Inc.
BP-KIT-060	CIVCO Medical Instruments Co., Inc.
BP-KIT-024	PROTEK medical Products, Inc.
BP-KIT-046	PROTEK medical Products, Inc.
BP-KIT-049	PROTEK medical Products, Inc.
BP-KIT-052	PROTEK medical Products, Inc.
BP-KIT-058	PROTEK medical Products, Inc.
BP-KIT-059	PROTEK medical Products, Inc.
BP-KIT-068	PROTEK medical Products, Inc.
BP-KIT-029	CIVCO Medical Instruments Co., Inc.
SW Option	
4D	SAMSUNG MEDISON CO., LTD.
3D XI	SAMSUNG MEDISON CO., LTD.
CW Function	SAMSUNG MEDISON CO., LTD.
Cardiac Measurement	SAMSUNG MEDISON CO., LTD.
DICOM	SAMSUNG MEDISON CO., LTD.
MultiVision	SAMSUNG MEDISON CO., LTD.
XI STIC	SAMSUNG MEDISON CO., LTD.
Auto IMT	SAMSUNG MEDISON CO., LTD.
Elastoscan	SAMSUNG MEDISON CO., LTD.
Panoramic	SAMSUNG MEDISON CO., LTD.
Stress Echo	SAMSUNG MEDISON CO., LTD.
Strain	SAMSUNG MEDISON CO., LTD.
HDVI	SAMSUNG MEDISON CO., LTD.
VolumeNT	SAMSUNG MEDISON CO., LTD.
ADVR	SAMSUNG MEDISON CO., LTD.
Options	

Product Description	Manufacturer
UGEO HM70 CART	SAMSUNG MEDISON CO., LTD.
HM70A CART	SAMSUNG MEDISON CO., LTD.
Extended Battery	Elentec Co., Ltd
Extended Power Pack	Daeam Elecom Co., Ltd
Foot Switch (FSU-3000S)	WHANAM Electronics Co., Ltd.
Foot Switch (FSU-3000SM)	WHANAM Electronics Co., Ltd.
ECG Module (ECG-USB1)	Norav Medical Ltd.
Rolling Case (Carrier, TRAVEL CASE)	Meejee Corporation
Printer (UP-X898MD)	Sony Corporation
Printer (UP-D898MD)	Sony Corporation
Magnetizer	Ezono AG
Phantom - Needle Pilot	FCU Co., Ltd
CP Skin	Chalgomu Keyboard Co., Ltd