

EU Declaration of Conformity

For the following

Product name : Diagnostic Ultrasound Apparatus
Model(s) name : HERA W9
Transducer : CA1-7A, CA2-9A, CA3-10A, CV1-8A, EA2-11B, EV3-10B, VR5-9, E3-12A, CF4-9, L3-12A, LA2-9A, LA4-18B, PM1-6A, PA3-8B, PA4-12B, EA2-11AR, EA2-11AV, EV2-10A, LA2-14A, PA1-5A
Risk Class : Ila
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 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	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

2021-04-19

(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 2021-04-19

Product Description	Manufacturer
HERA W9	SAMSUNG MEDISON CO., LTD.
Probe & Biopsy	
CA1-7A	SAMSUNG MEDISON CO., LTD.
CA2-9A	SAMSUNG MEDISON CO., LTD.
CA3-10A	SAMSUNG MEDISON CO., LTD.
EA2-11B	SAMSUNG MEDISON CO., LTD.
VR5-9	SAMSUNG MEDISON CO., LTD.
E3-12A	SAMSUNG MEDISON CO., LTD.
CF4-9	SAMSUNG MEDISON CO., LTD.
EV3-10B	SAMSUNG MEDISON CO., LTD.
CV1-8A	SAMSUNG MEDISON CO., LTD.
L3-12A	SAMSUNG MEDISON CO., LTD.
LA2-9A	SAMSUNG MEDISON CO., LTD.
LA4-18B	SAMSUNG MEDISON CO., LTD.
PM1-6A	SAMSUNG MEDISON CO., LTD.
PA3-8B	SAMSUNG MEDISON CO., LTD.
PA4-12B	SAMSUNG MEDISON CO., LTD.
EA2-11AR	SAMSUNG MEDISON CO., LTD.
EA2-11AV	SAMSUNG MEDISON CO., LTD.
EV2-10A	SAMSUNG MEDISON CO., LTD.
LA2-14A	SAMSUNG MEDISON CO., LTD.
PA1-5A	SAMSUNG MEDISON CO., LTD.
BP-KIT-029	CIVCO Medical Instruments Co., Inc.
BP-KIT-041	CIVCO Medical Instruments Co., Inc.
BP-KIT-043	CIVCO Medical Instruments Co., Inc.
BP-KIT-053	PROTEK medical Products, Inc.

Product Description	Manufacturer
BP-KIT-054	PROTEK medical Products, Inc.
BP-KIT-057	CIVCO Medical Instruments Co., Inc.
BP-KIT-058	PROTEK medical Products, Inc.
BP-KIT-059	PROTEK medical Products, Inc.
BP-KIT-060	CIVCO Medical Instruments Co., Inc.
BP-KIT-065	CIVCO Medical Instruments Co., Inc.
BP-KIT-066	CIVCO Medical Instruments Co., Inc.
BP-KIT-067	CIVCO Medical Instruments Co., Inc.
BP-KIT-069	CIVCO Medical Instruments Co., Inc.
BP-KIT-071	CIVCO Medical Instruments Co., Inc.
BP-KIT-076	PROTEK medical Products, Inc.
BP-KIT-077	CIVCO Medical Instruments Co., Inc.
BP-KIT-078	CIVCO Medical Instruments Co., Inc.
BP-KIT-079	CIVCO Medical Instruments Co., Inc.
BP-KIT-080	CIVCO Medical Instruments Co., Inc.
BP-KIT-081	CIVCO Medical Instruments Co., Inc.
BP-KIT-082	CIVCO Medical Instruments Co., Inc.
BP-KIT-085	PROTEK medical Products, Inc.
BP-KIT-086	PROTEK medical Products, Inc.
BP-KIT-088	PROTEK medical Products, Inc.
BP-KIT-089	PROTEK medical Products, Inc.
BP-KIT-090	PROTEK medical Products, Inc.
SW Option	
5D CNS+	SAMSUNG MEDISON CO., LTD.
5D Follicle	SAMSUNG MEDISON CO., LTD.
5D Heart Color	SAMSUNG MEDISON CO., LTD.

Product Description	Manufacturer
5D LB	SAMSUNG MEDISON CO., LTD.
5D Limb Vol.	SAMSUNG MEDISON CO., LTD.
5D NT	SAMSUNG MEDISON CO., LTD.
ADVR	SAMSUNG MEDISON CO., LTD.
AutoIMT+	SAMSUNG MEDISON CO., LTD.
CEUS+	SAMSUNG MEDISON CO., LTD.
CrystalVue	SAMSUNG MEDISON CO., LTD.
CW Function	SAMSUNG MEDISON CO., LTD.
E-Breast	SAMSUNG MEDISON CO., LTD.
E-Cervix	SAMSUNG MEDISON CO., LTD.
EastoScan+	SAMSUNG MEDISON CO., LTD.
E-Thyroid	SAMSUNG MEDISON CO., LTD.
HDVI	SAMSUNG MEDISON CO., LTD.
IOTA-ADNEX	SAMSUNG MEDISON CO., LTD.
Mobile Export	SAMSUNG MEDISON CO., LTD.
MobileSleep	SAMSUNG MEDISON CO., LTD.
MV-Flow	SAMSUNG MEDISON CO., LTD.
Panoramic	SAMSUNG MEDISON CO., LTD.
SonoSync	SAMSUNG MEDISON CO., LTD.
RealisticVue	SAMSUNG MEDISON CO., LTD.
S-Detect™ for Breast	SAMSUNG MEDISON CO., LTD.
S-Detect™ for Thyroid	SAMSUNG MEDISON CO., LTD.
Smart 4D+	SAMSUNG MEDISON CO., LTD.
Software Trial	SAMSUNG MEDISON CO., LTD.
ViewAssist	SAMSUNG MEDISON CO., LTD.
Slice A	SAMSUNG MEDISON CO., LTD.
Options	
ECG Module (ECG-USB1)	Norav Medical Ltd.

Product Description	Manufacturer
Foot Switch (USB) (FSU-3000 SM)	Whanam Electronics Co., Ltd.
Gel Warmer (SSGW_1000)	JCWell
Gel Warmer	Seong Ji Industrial Co., Ltd
Aquasonic 100 Ultrasound Transmission Gel	Parker Laboratories Inc.
Printer (UP-X898MD)	Sony Corporation
Printer (UP-D898MD)	Sony Corporation
Endoprobe holder	DAEJIN CHEMICAL CO.,LTD.