

EU Declaration of Conformity

For the following

Product name : Ultrasound Scanner
Model(s) name : V6
Risk Class : IIa
Basic UDI-DI : 880972578USS001X6
Document Revision: 3

We hereby declare under our sole responsibility, that the product above is in compliance with the MDR Regulation (EU) 2017/745. It is subject to the conformity assessment procedures set out in Annex IX(Chapter I and III) of the MDR Regulation (EU) 2017/745 under the supervision of TUV SUD (Notified Body No.: 0123, EU Quality Management System Certificate (MDR) No. G10 076726 0012).

EN ISO 15223-1:2021	EN 1041:2008
EN ISO 13485:2016/A11:2021	EN ISO 10993-1:2009
EN ISO 14971:2019	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/A1:2015	EN 60601-2-18:2015

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:**

SRN: KR-MF-000011620
SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108,
REPUBLIC OF KOREA

2023-07-25

(Place and date of issue)

Scully Kim /Regulatory Affairs Manager

(Name and signature of authorized person)

**Authorised Representative:**

SRN: DE-AR-000007005
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

Ultrasound Scanner	Manufacturer
V6	SAMSUNG MEDISON CO., LTD
SW option	
V6 2D Follicle™	SAMSUNG MEDISON CO., LTD
V6 5D CNS+™	SAMSUNG MEDISON CO., LTD
V6 5D Follicle™	SAMSUNG MEDISON CO., LTD
V6 5D Heart Color™	SAMSUNG MEDISON CO., LTD
V6 5D LB™	SAMSUNG MEDISON CO., LTD
V6 5D Limb Vol.™	SAMSUNG MEDISON CO., LTD
V6 5D NT™	SAMSUNG MEDISON CO., LTD
V6 ADVR™	SAMSUNG MEDISON CO., LTD
V6 ArterialAnalysis™	SAMSUNG MEDISON CO., LTD
V6 AutoIMT+	SAMSUNG MEDISON CO., LTD
V6 AutoEF	SAMSUNG MEDISON CO., LTD
V6 BiometryAssist™	SAMSUNG MEDISON CO., LTD
V6 Cardiac Measurement	SAMSUNG MEDISON CO., LTD
V6 CEUS+	SAMSUNG MEDISON CO., LTD
V6 CrystalVue	SAMSUNG MEDISON CO., LTD
V6 CrystalVue Flow™	SAMSUNG MEDISON CO., LTD
V6 CW Function	SAMSUNG MEDISON CO., LTD
V6 DICOM	SAMSUNG MEDISON CO., LTD
V6 E-Cervix™	SAMSUNG MEDISON CO., LTD
V6 E-Strain™	SAMSUNG MEDISON CO., LTD
V6 ElastoScan+™	SAMSUNG MEDISON CO., LTD
V6 Expended Storage (1TB)	SAMSUNG MEDISON CO., LTD
V6 EzExam+™	SAMSUNG MEDISON CO., LTD
V6 EzHRI™	SAMSUNG MEDISON CO., LTD
V6 HeartAssist™	SAMSUNG MEDISON CO., LTD
V6 HDVI™	SAMSUNG MEDISON CO., LTD
V6 HQ-Vision™	SAMSUNG MEDISON CO., LTD
V6 IOTA-ADNEX	SAMSUNG MEDISON CO., LTD
V6 LaborAssist™	SAMSUNG MEDISON CO., LTD
V6 LumiFlow™	SAMSUNG MEDISON CO., LTD
V6 Mobile Export	SAMSUNG MEDISON CO., LTD
V6 MV-Flow™	SAMSUNG MEDISON CO., LTD
V6 NeedleMate+™	SAMSUNG MEDISON CO., LTD
V6 NerveTrack™	SAMSUNG MEDISON CO., LTD
V6 Panoramic+	SAMSUNG MEDISON CO., LTD

V6 QUS™ (TAI™, TSI™)	SAMSUNG MEDISON CO., LTD
V6 RealisticVue™	SAMSUNG MEDISON CO., LTD
V6 S-Detect™ for Breast	SAMSUNG MEDISON CO., LTD
V6 S-Detect™ for Thyroid	SAMSUNG MEDISON CO., LTD
V6 S-Fusion™	SAMSUNG MEDISON CO., LTD
V6 S-Shearwave Imaging™	SAMSUNG MEDISON CO., LTD
V6 Smart 4D	SAMSUNG MEDISON CO., LTD
V6 SonoSync™	SAMSUNG MEDISON CO., LTD
V6 Strain+	SAMSUNG MEDISON CO., LTD
V6 StressEcho	SAMSUNG MEDISON CO., LTD
V6 System Activation	SAMSUNG MEDISON CO., LTD
V6 UterineAssist™	SAMSUNG MEDISON CO., LTD
V6 ViewAssist™	SAMSUNG MEDISON CO., LTD
V6 XI STIC	SAMSUNG MEDISON CO., LTD
V6 SEE Stream	SAMSUNG MEDISON CO., LTD