SAMSUNG

EU Declaration of Conformity

For the following

Product name :	Ultrasound Scanner
Model(s) name :	XV7
Risk Class :	IIa
Basic UDI-DI :	880972578USS001X6
Document Revision:	0

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

Scully KIM

2023-01-25
(Place and date of issue)

Scully Kim /Regulatory Affairs Manager
(Name and signature of authorized person)

EC REP **Authorised Representative:**

SRN: DE-AR-000007005
Samsung Electronics GmbH
Am Kronberger Hang 6,
65824 Schwalbach am Taunus, Germany

Digitally signed by Şarco Alexandru
Date: 2023.05.23 08:43:50 EEST
Reason: MoldSign Signature
Location: Moldova

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.

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APPENDIX

Ultrasound Scanner	Manufacturer
XV7	SAMSUNG MEDISON CO., LTD
SW option	
XV7 2D Follicle™	SAMSUNG MEDISON CO., LTD
XV7 5D CNS+™	SAMSUNG MEDISON CO., LTD
XV7 5D Follicle™	SAMSUNG MEDISON CO., LTD
XV7 5D Heart Color™	SAMSUNG MEDISON CO., LTD
XV7 5D LB™	SAMSUNG MEDISON CO., LTD
XV7 5D Limb Vol. ™	SAMSUNG MEDISON CO., LTD
XV7 5D NT™	SAMSUNG MEDISON CO., LTD
XV7 ADVR™	SAMSUNG MEDISON CO., LTD
XV7 ArterialAnalysis™	SAMSUNG MEDISON CO., LTD
XV7 AutoIMT+	SAMSUNG MEDISON CO., LTD
XV7 AutoEF	SAMSUNG MEDISON CO., LTD
XV7 BiometryAssist ™	SAMSUNG MEDISON CO., LTD
XV7 Cardiac Measurement	SAMSUNG MEDISON CO., LTD
XV7 CEUS+	SAMSUNG MEDISON CO., LTD
XV7 CrystalVue	SAMSUNG MEDISON CO., LTD
XV7 CrystalVue Flow ™	SAMSUNG MEDISON CO., LTD
XV7 CW Function	SAMSUNG MEDISON CO., LTD
XV7 DICOM	SAMSUNG MEDISON CO., LTD
XV7 E-Cervix ™	SAMSUNG MEDISON CO., LTD
XV7 E-Strain ™	SAMSUNG MEDISON CO., LTD
XV7 ElastoScan+ ™	SAMSUNG MEDISON CO., LTD
XV7 Expended Storage (1TB)	SAMSUNG MEDISON CO., LTD
XV7 EzExam+ ™	SAMSUNG MEDISON CO., LTD
XV7 EzHRI ™	SAMSUNG MEDISON CO., LTD
XV7 HeartAssist ™	SAMSUNG MEDISON CO., LTD
XV7 HDVI ™	SAMSUNG MEDISON CO., LTD
XV7 HQ-Vision ™	SAMSUNG MEDISON CO., LTD
XV7 IOTA-ADNEX	SAMSUNG MEDISON CO., LTD
XV7 LaborAssist ™	SAMSUNG MEDISON CO., LTD
XV7 LumiFlow ™	SAMSUNG MEDISON CO., LTD
XV7 Mobile Export	SAMSUNG MEDISON CO., LTD
XV7 MPI+	SAMSUNG MEDISON CO., LTD
XV7 MV-Flow ™	SAMSUNG MEDISON CO., LTD
XV7 NeedleMate+ ™	SAMSUNG MEDISON CO., LTD
XV7 NerveTrack ™	SAMSUNG MEDISON CO., LTD

XV7 Panoramic+	SAMSUNG MEDISON CO., LTD
XV7 QUS™ (TAI™, TSI™)	SAMSUNG MEDISON CO., LTD
XV7 RealisticVue™	SAMSUNG MEDISON CO., LTD
XV7 S-Detect™ for Breast	SAMSUNG MEDISON CO., LTD
XV7 S-Detect™ for Thyroid	SAMSUNG MEDISON CO., LTD
XV7 S-Fusion™	SAMSUNG MEDISON CO., LTD
XV7 S-Shearwave Imaging™	SAMSUNG MEDISON CO., LTD
XV7 Smart 4D	SAMSUNG MEDISON CO., LTD
XV7 SonoSync™	SAMSUNG MEDISON CO., LTD
XV7 Strain+	SAMSUNG MEDISON CO., LTD
XV7 StressEcho	SAMSUNG MEDISON CO., LTD
XV7 System Activation	SAMSUNG MEDISON CO., LTD
XV7 UterineAssist™	SAMSUNG MEDISON CO., LTD
XV7 ViewAssist™	SAMSUNG MEDISON CO., LTD
XV7 XI STIC	SAMSUNG MEDISON CO., LTD
XV7 SEE Stream	SAMSUNG MEDISON CO., LTD

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 076726 0012 Rev. 00

Manufacturer:

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

Authorized Representative:

Samsung Electronics GmbH
Am Kronberger Hang 6, 65824 Schwalbach am Taunus,
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 74956580

Valid from: 2020-07-06
Valid until: 2025-07-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-07-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 076726 0012 Rev. 00

Device Group:	Z110401 - ULTRASOUND SCANNERS
Classification:	IIa
Intended Purpose:	-/-
The validity of this certificate depends on conditions and/or is limited to the following:	None

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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