

EU Declaration of Conformity

For the following

Product name : Ultrasound Scanner
Model(s) name : V8
Risk Class : IIa
Basic UDI-DI : 880972578USS001X6
Document Revision: 2

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 15223-1:2016	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	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

2022-01-27

(Place and date of issue)

YongHo Lee / Vice President

(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.