

# EU Declaration of Conformity

**For the following**

**Product name :** Diagnostic Ultrasound Apparatus  
**Model(s) name :** HS30  
**Transducer :** LN5-12, L5-12/50, CF4-9 C2-5, C2-8, PN2-4 , EVN4-9 ER4-9, DP2B ,  
SP3-8, VN4-8, EV2-10A, CA2-6BM  
**Risk Class :** IIa  
**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 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             |                                     |

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

2021-04-28

(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 2021-04-28

| Product Description       | Manufacturer                        |
|---------------------------|-------------------------------------|
| HS30                      | SAMSUNG MEDISON CO., LTD.           |
| <b>Probe &amp; Biopsy</b> |                                     |
| LN5-12                    | SAMSUNG MEDISON CO., LTD.           |
| L5-12/50                  | SAMSUNG MEDISON CO., LTD.           |
| CF4-9                     | SAMSUNG MEDISON CO., LTD.           |
| C2-5                      | SAMSUNG MEDISON CO., LTD.           |
| C2-8                      | SAMSUNG MEDISON CO., LTD.           |
| PN2-4                     | SAMSUNG MEDISON CO., LTD.           |
| EVN4-9                    | SAMSUNG MEDISON CO., LTD.           |
| ER4-9                     | SAMSUNG MEDISON CO., LTD.           |
| DP2B                      | SAMSUNG MEDISON CO., LTD.           |
| SP3-8                     | SAMSUNG MEDISON CO., LTD.           |
| VN4-8                     | SAMSUNG MEDISON CO., LTD.           |
| EV2-10A                   | SAMSUNG MEDISON CO., LTD.           |
| CA2-6BM                   | SAMSUNG MEDISON CO., LTD.           |
| BP-KIT-040                | PROTEK medical Products, Inc.       |
| BP-KIT-047                | PROTEK medical Products, Inc.       |
| BP-KIT-045                | PROTEK medical Products, Inc.       |
| BP-KIT-035                | PROTEK medical Products, Inc.       |
| BP-KIT-061                | CIVCO Medical Instruments Co., Inc. |
| BP-KIT-024                | PROTEK medical Products, Inc.       |
| BP-KIT-049                | PROTEK medical Products, Inc.       |
| BP-KIT-086                | PROTEK medical Products, Inc.       |
| BP-KIT-085                | PROTEK medical Products, Inc.       |
| <b>SW Option</b>          |                                     |
| DICOM                     | SAMSUNG MEDISON CO., LTD.           |

| Product Description       | Manufacturer                 |
|---------------------------|------------------------------|
| EzExam+                   | SAMSUNG MEDISON CO., LTD.    |
| MultiVision               | SAMSUNG MEDISON CO., LTD.    |
| CW Function               | SAMSUNG MEDISON CO., LTD.    |
| Cardiac Measurement       | SAMSUNG MEDISON CO., LTD.    |
| Strain+                   | SAMSUNG MEDISON CO., LTD.    |
| EzAssist                  | SAMSUNG MEDISON CO., LTD.    |
| NeedleMate+               | SAMSUNG MEDISON CO., LTD.    |
| Mobile Export             | SAMSUNG MEDISON CO., LTD.    |
| Auto IMT+                 | SAMSUNG MEDISON CO., LTD.    |
| ElastoScan                | SAMSUNG MEDISON CO., LTD.    |
| Panoramic                 | SAMSUNG MEDISON CO., LTD.    |
| Freehand 3D               | SAMSUNG MEDISON CO., LTD.    |
| 4D                        | SAMSUNG MEDISON CO., LTD.    |
| XI STIC                   | SAMSUNG MEDISON CO., LTD.    |
| 3D XI                     | SAMSUNG MEDISON CO., LTD.    |
| System Activation         | SAMSUNG MEDISON CO., LTD.    |
| LaborAssist               | SAMSUNG MEDISON CO., LTD.    |
| 2D NT                     | SAMSUNG MEDISON CO., LTD.    |
| Windows 10                | SAMSUNG MEDISON CO., LTD.    |
| <b>Options</b>            |                              |
| ECG Module (ECG-USB1)     | Norav Medical Ltd.           |
| Foot Switch (FSU-3000 SM) | Whanam Electronics Co., Ltd. |
| Gel warmer                | JCWell                       |