EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

We:

Manufacturer

GE Vingmed Ultrasound AS
Strandpromenaden 45,
3191 Horten, Norway
Single Registration Number (SRN): NO-MF-000000553

Manufacturing Sites

GE Vingmed Ultrasound AS
Strandpromenaden 45
3191 Horten, Norway

GE Medical Systems (China) Co., Ltd.
No. 19, Changjiang Road
Wuxi National Hi-Tech Dev.Zone
214028 Jiangsu, China

Declare under our sole responsibility that the device:

Vivid S70N v206, Vivid S60N version 206 and Vivid S v203, v204, v205 to v206 UPG

Basic UDI-DI: 8406821BUG00252H9

Identification number: BD000100, BD000105, BD000110, BD000115, BD200145

Intended Purpose: The Vivid S70N, Vivid S60N is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

GMDN Code: 40763

GMDN Description: Ultrasound system, imaging, cardiovascular

Class: IIa

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis) and Rule 11 (Software)

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it, and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), and the directive 2014/53/EU on the radio equipment (RED)

Date of issue: 04-OCT-2022
Place of issue: Horten
Name: Charlotte Jørgensen
Function: Sr. Regulatory Affairs Leader

Signature:

Reference of the Declaration: DOC2656827

This conformity is based on the following elements:

- Technical Documentation reference: **DOC2644852**, of the product to which this declaration relates.

- EC certificate **G10 023782 0130**
    - Conformity assessment procedure followed: Annex IX excluding chapter II
    - Delivered by **TÜV SÜD Product Service GmbH**, Ridlerstrasse 65, 80339 Munich, Germany (Notified Body 0123)

Date of issue: 04-OCT-2022
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Function: Sr. Regulatory Affairs Leader

Signature:

This EC declaration of conformity supersedes the previous declaration dated 06-SEP-2022

Reference of the Declaration: DOC2656827

ADDENDUM TO THE EC DECLARATION OF CONFORMITY for Vivid S70N / Vivid S60N (v206)

Commercial Device Name w. version[1]	Device Part #[2]	GEHC Cat #[3]	Description
Vivid S70N v206	BD000100	H45611NC	Vivid S70N v206 (manufactured in Norway)
		H45611MY	Vivid S70N v206 eD (manufactured in Norway)
		H45611WR	Vivid S70N v206 (with Dimension, manufactured in Norway
		H45611WU	Vivid S70N v206 eD (with Dimension, manufactured in Norway)
Vivid S60N v206	BD000105	H45611ND	Vivid S60N v206 (manufactured in Norway
		H45611MX	Vivid S60N v206 eD (manufactured in Norway)
Vivid S70N v206CH	BD000110	H45611NA	Vivid S70N v206CH (manufactured in China)
		H45611MW	Vivid S70N v206CH eD (manufactured in China)
		H45611WS	Vivid S70N v206CH (with Dimension, manufactured in China)
		H45611WV	Vivid S70N v206CH eD (with Dimension, manufactured in China)
Vivid S60N v206CH	BD000115	H45611NB	Vivid S60N v206CH (manufactured in China)
		H45611MV	Vivid S60N v206 CH eD (manufactured in China)
Vivid S v203, v204, v205 to v206 UPG	BD200145	H45611NE	Vivid S v203, v204, v205 to v206 UPG
		H45611NF	Vivid S v203, v204, v205 to v206 UPG eD

OPTIONS CONSOLS	GEHC Cat #[3]	Vivid S70N	Vivid S60N
Smart Stress	H45551WK	X	X
AI Auto Measure - 2D	H45601YX	X	X
AI Auto Measure - Spectrum Recognition	H45601YY	X	X
AutoEF 3.0	H45601YK	X	X
Easy AutoEF	H45611MM	X	X
Easy AFI LV	H45611MP	X	X
AFI 3.0	H45601WG	X	X
AFI RV	H45601TT	X	X
AFI LA	H45601TU	X	X
Advanced Qscan imaging	H45561RK	X	X
AdvancedContrast Imaging	H45571GY	X	X
Vascular/Abdominal Contrast	H45561MZ	X	X
4D	H45581PG	X	-
HD Color	H45601ZG	X	-
4D Auto MVQ	H45591AD	X	-
4D Auto AVQ	H45581CL	X	-
4D Auto RVQ	H45591AE	X	-
4D Markers	H45601GK	X	-
Remote Viewing	H45611MR	X	-
Probe Check	H45611MS	X	X
GE Ultrasound DICOM viewer	H48532BS	X	X
Streaming	H45601GJ	X	X
ICE interface	H45591RE	X	X
CartoSound interface	H45591RF	X	X
Tricefy Uplink	H45601GW	X	X

Table Legend: X = Available with this Ultrasound Console; - = Not available with this Ultrasound Console

Notes used in the table :

1. Commercial Device Name is usually affixed to the device(s) in the form of a product identification or rating label under the symbol "REF")
2. Device Part # identifies the device(s) in the manufacturer's design, manufacturing, and service documentation.
3. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

Horten, 04-OCT-2022

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Sr. Regulatory Affairs Leader

PROBES w. Accessories [1]	TYPE [2]	GEHC Cat # [3]	Vivid S70N	Vivid S60N
3Sc-RS	BF	H45041DL	X	X
M5Sc-D	BF	H44901AE	X	X
6S-D	BF	H45021RR	X	X
12S-D	BF	H45021RT	X	X
6VT-D	BF	H45581BJ	X	X
6Tc-RS	BF	H45551ZE	X	X
9T-RS	BF	H45531YM	X	X
10T-D	BF	H44901AH	X	X
9L-D	BF	H40442LM	X	X
11L-D	BF	H40432LN	X	X
C1-6-D	BF	H40472LT	X	X
C2-9-D	BF	H40462LN	X	X
C3-10-D	BF	H40482LB	X	X
C1-5-D	BF	H40452LE	X	X
IC5-9-D	BF	H40442LK	X	X
P2D	BF	H4830JE	X	X
P6D	BF	H4830JG	X	X
L8-18i-D	BF	H40452LL	X	X
ML6-15-D	BF	H40452LG	X	X
4Vc-D	BF	H40482LS	X	-
M5Sc-D Biopsy kit	N/A	H45561FC	X	X
3Sc-RS Biopsy Kit	N/A	H46222LC	X	X
9L-D Biopsy Kit	N/A	H4906BK	X	X
11L-D Biopsy kit	N/A	H40432LC	X	X
C1-5-D Biopsy kit	N/A	H40432LE	X	X
C1-6-D Biopsy kit	N/A	H4913BB	X	X
C2-9-D Biopsy kit	N/A	H4913BA	X	X
IC5-9-D Biopsy kit	N/A	E8385MJ	X	X
ML6-15-D Biopsy kit	N/A	H40432LJ	X	X
4Vc-D MultiAngle Biopsy kit	N/A	H40482LP	X	-
TEE Storage Rack	N/A	H45551NM	X	X
TEE Clip-On Bite Guard Adult	N/A	H45511EE	X	X
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB	X	X
TEE Conventional Bite Guard Pediatric	N/A	H45521JG	X	X
TEE Conventional Bite Guard Adult	N/A	H45521JH	X	X
Adult TEE Scanhead Protection Cover	N/A	H45521CK	X	X
Pediatric TEE Scanhead Protection Cover	N/A	H45541RN	X	X
Bite Hole Indicator	N/A	H45531HS	X	X
ICEcord-RS w. Ferrite filter	N/A	H48952AR	X	X
AcuNav™ G 8F	CF	N/A Part No 10135910	X	X
AcuNav™ G 10F	CF	N/A Part No 10043342	X	X
SoundStar eco 8FG	CF	N/A Part No M-5723-18 (EU ref no.: 10439236)	X	X
SoundStar eco 10FG	CF	N/A Part No 10135910	X	X
SoundStar 3D 10F	CF	N/A Part No SNDSTR10G	X	X
Carto® 3	N/A	N/A Part No FG-5400-00	X	X

Notes : 1. Probes and accessories may carry the CE-mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Vingmed Ultrasound AS has verified the mutual compatibility of the devices in combination with Vivid S60N/S70N in accordance with the manufacturers' instructions and included relevant information to users with the Vivid S60N/S70N instructions for use. This activity was subject to appropriate methods of internal monitoring, verification, and validation.

2. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

3. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

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I/O [1]	GEHC Cat # [2]	Vivid S70N	Vivid S60N
ECG cable, adult, AHA	H45571PY	X	X
ECG lead set, adult, AHA	H45571PZ	X	X
ECG cable, adult, IEC	H45571RA	X	X
ECG lead set, adult, IEC	H45571RB	X	X
Lead/electrode neo AHA 600	H45571RJ	X	X
Lead/electrode neo IEC 600	H45571RK	X	X
Adapter, ECG 3-lead	H45571RL	X	X
Ext ECG Cable	H45021LL	X	X
ECG cable, adult, AHA	H45601SB	X	X
ECG lead set, adult, AHA	H45601SC	X	X
ECG cable, adult, IEC	H45601SD	X	X
ECG lead set, adult, IEC	H45601SE	X	X
ECG cable, neo, AHA	H45601SF	X	X
ECG cable, neo, IEC	H45601SG	X	X
Lead/electrode neo AHA 600	H45601SH	X	X
Lead/electrode neo IEC 600	H45601SJ	X	X
Adapter, ECG 3-lead	H45601SK	X	X

ACCESSORIES [1]	GEHC Cat # [2]	Vivid S70N	Vivid S60N
USB B/W video printer	H45601YZ	X	X
USB B/W printer support	H45601ZB	X	X
DVD RW	H45601ZC	X	X
USB color video printer	H45561AA	X	X
Col Laser Printer 220-240V	H45541MJ	X	X
Col Laser Printer 100-120V	H45541MH	X	X
Smart Standby - Battery	H45051AB	X	X
Storage box	H45051AC	X	X
Tripedal footswitch	H46732LF	X	X
Stereo Glasses for 3D visualization, Set	H45551MH	X	-
Spectacle Casing	H45551MJ	X	
Anachrome 3D glasses	H45551MK	X	
Anachrome 3D glasses Clip-On Flips	H45551ML	X	
Wi-Fi kit / Wireless USB Adapter	H45591HS	X	X
Isolated HDMI converter/splitter	H48982AN	X	X
UPS 220-240V 50/60Hz	H45611JF	X	X
UPS Support Kit	H45611JG	X	X

Notes:
1. I/O and Accessories may carry the CE-mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer. GE Vingmed Ultrasound AS has verified the mutual compatibility of the devices in combination with Vivid S60N/S70N in accordance with the manufacturers' instructions and included relevant information to users with the Vivid S60N/S70N Instructions for use. This activity was subject to appropriate methods of internal monitoring, verification, and validation.
2. GEHC Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

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