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

Declare under our sole responsibility that the devices:

Vivid E80 v206, Vivid E90 v206, Vivid E95 v206, Vivid E v203 v204 to v206 UPG

Basic UDI-DI: 8406821BUG00253HB

Identification number: GD000100, GD000110, GD000120, GD200145

Intended Purpose: The Vivid E80, Vivid E90, Vivid E95, Vivid E v203 v204 to v206 UPG are general-purpose ultrasound systems or version upgrade kits for general-purpose ultrasound systems, specialized for use in cardiac imaging. Intended for ultrasound imaging, measurement, display and analysis of the human body and fluid.

GMDN Code: 40763

GMDN Description: Ultrasound system, imaging, cardiovascular.

EMDN Code: Z11040102

Class: IIa

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis).

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)

This conformity is based on the following elements:

- Technical Documentation reference: **DOC2491176**, 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**, identification number: 0123

SIGNATURE: [redacted]
Date of issue
Place of issue
Name:
Function:

Signature:

This EC declaration of conformity supersedes the previous declaration for Vivid E95, Vivid E90 and Vivid E80 version v206 dated August 31, 2022.

ADDENDUM TO EC DECLARATION OF CONFORMITY for Vivid E95, Vivid E90, Vivid E80 (v206)

Commercial Device Name w. version [1]	Device Part # [2]	GEHC Cat # [3]	Description
Vivid E95 v206	GD000100	H45611PP	Vivid E95 v206 with HDU
		H45611PK	Vivid E95 v206 with HDU eD
		H45611PV	Vivid E95 v206 with OLED
		H45611PG	Vivid E95 v206 with OLED eD
Vivid E90 v206	GD000110	H45611PQ	Vivid E90 v206 with HDU
		H45611PL	Vivid E90 v206 with HDU eD
		H45611PW	Vivid E90 v206 with OLED
		H45611PH	Vivid E90 v206 with OLED eD
Vivid E80 v206	GD000120	H45611PR	Vivid E80 v206 with HDU
		H45611PM	Vivid E80 v206 with HDU eD
		H45611PX	Vivid E80 v206 with OLED
		H45611PJ	Vivid E80 v206 with OLED eD
Vivid E v203 v204 to v206 UPG	GD200145	H45611PZ	Vivid E95 E90 E80 v204 to v206 UPG
		H45611QR	Vivid E95 E90 E80 v204 to v206 UPG with eD
		H45611QW	Vivid E95 v203 to v206 UPG
		H45611QS	Vivid E95 v203 to v206 UPG with eD
		H45611QX	Vivid E90 E80 v203 to v206 UPG
		H45611QT	Vivid E90 E80 v203 to v206 UPG with eD

OPTIONS CONSOLS	GEHC Cat # [3]
Easy AutoEF	H45611MM
Easy AFI LV	H45611MP
Remote Viewing	H45611MR
Vascular Contrast	H45561MZ
Probe Check	H45611MS
Adv. Contrast Imaging	H45571GY
AFI 3.0	H45601WG
AFI RV	H45601TT
AFI LA	H45601TU
AI Auto Measure	H45601TX
4D Strain and LV Mass	H45561NB
4D Auto AVQ	H45581CL
Stress	H45561NC
Auto EF 3.0	H45601YK
4D Auto TVQ	H45601TW
HDlive, HDcolor and FlexiLight	H45601TZ
4D Auto MVQ	H45591AD
4D Auto RVQ	H45591AE
DICOM viewer	H48532BS
Blood Speckle Imaging (BSI)	H45591AF
Myocardial Work	H45591AG
CT Fusion	H45601GN
4D Markers E-series	H45601GP
4D Auto LAQ	H45601GR
Streaming E-series	H45601GT

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.

[redacted]

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PROBES w. Accessories [2]	TYPE [3]	GEHC Cat # [1]
4V-D	BF	H40018BT
4Vc-D	BF	H40482LS
6Vc-D	BF	H44901AQ
M5Sc-D	BF	H44901AE
6S-D	BF	H45021RR
12S-D	CF	H45021RT
9L-D	BF	H40442LM
11L-D	BF	H40432LN
ML6-15-D	BF	H40452LG
C1-6-D	BF	H40472LT
C2-9-D	BF	H40462LN
8C	BF	H40412LJ
iC5-9-D	BF	H40442LK
C3-10-D	BF	H40482LB
L8-18i-D	BF	H40452LL
6Tc	BF	H45551ZD
6Tc-RS [4]	BF	H45551ZE
6VT-D	BF	H45581BJ
9VT-D	BF	H45581CS
9T	BF	H45521DY
9T-RS [4]	BF	H45531YM
10T-D	BF	H44901AH
P2D	BF	H4830JE
P6D	BF	H4830JG
TEE Storage Rack	N/A	H45551NM
TEE PROBE ADAPTER FOR 6T-RS/9T-RS	N/A	H45541PX
TEE Scan head Protection Cover	N/A	H45521CK
Ped TEE Scan head Protection Cover	N/A	H45541RN
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB
TEE Conventional Bite Guard Ped.	N/A	H45521JG
Bite Hole Indicator	N/A	H45531HS
4Vc-D Multi Angle Biopsy kit	N/A	H40482LP
C1-6-D Biopsy bracket	N/A	H4913BB
C2-9-D Biopsy bracket	N/A	H4913BA
iC5-9-D Needle guide	N/A	E8385MJ
9L Biopsy guide starter kit	N/A	H4906BK
12L-RS / 11L-D Multi biopsy guide	N/A	H40432LC
M5Sc-D Biopsy kit	N/A	H45561FC
ML6-15 Biopsy kit	N/A	H40432LJ

Notes used in the table:

1. 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.
2. 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 E95/E90/E80 in accordance with the manufacturers' instructions and included relevant information to users with the Vivid E95/E90/E80 instructions for use. This activity was subject to appropriate methods of internal monitoring, verification, and validation.
3. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.
4. The probes 6Tc-RS and 9T-RS can only be used on Vivid E95/E90/E80 when used together with the TEE Probe Adapter –RS, H45541PX. The adapter itself is not an applied part.

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I/O [3]	GEHC Cat # [2]	
ECG cable, adult, AHA	H45571PY / H45601SB	
ECG lead set, adult, AHA	H45571PZ / H45601SC	
ECG cable, adult, IEC	H45571RA / H45601SD	
ECG lead set, adult, IEC	H45571RB / H45601SE	
ECG cable, neo, AHA	H45571RD / H45601SF	
ECG cable, neo, IEC	H45571RE / H45601SG	
Lead/electr neo AHA 600	H45571RJ / H45601SH	
Lead/electr neo IEC 600	H45571RK / H45601SJ	
Adapter, ECG 3-lead	H45571RL / H45601SK	
Adapter for Pressure Xducer	H45581AF	
Adapter for MA-300 Heart Sound microphone	H45571GB	
ACCESSORIES [3]	**GEHC Cat # [2]**	
View-X	H45591AK	
B&W printer, digital with USB	H45601RU	
Vivid E-series BW printer, DC version	H45611QY	
Color Laser Printer 220V	H45541MJ	
Color Video Printer	H45561AA	
Installation for printers	H45541MK	
ECG Cable set	H45521AL	
Tripedal footswitch	H46732LF	
USB Memory Key 32GB	H45581NA	
External Digital Video Stream Recorder	H45581EL	
Protective Cover Vivid Expert	H45551NJ	
Spectacle Casing	H45551MJ	
Anacrome 3D glasses	H45551MK	
Anacrome 3D glasses Clip-On Flips	H45551ML	
Vivid Exx DVD Option ComExpress	H45601RT	
Wireless USB Adapter	H45591HS	
WiFi Kit Japan	H45601SN	
UPS 220-240V 50/60Hz	H45611JF	
UPS Support Kit	H45611LU	
UPGRADES [4]	**Device Part # [1]**	**GEHC Cat # [2]**
Vivid E80 4D Option	GC200426	H45581NY
Vivid E90 4D Option		H45581EM
Vivid E95 4D Option		H45601ZH
Vivid E80/E90/E80 v206 Software eDelivery	N/A	H45601YPED

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1. Device Part # identifies the device(s) in the manufacturer's design, manufacturing, and service documentation.
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.
3. 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 E95/E90/E80 in accordance with the manufacturers' instructions and included relevant information to users with the Vivid E95/E90/E80 instructions for use. This activity was subject to appropriate methods of internal monitoring, verification, and validation.
4. UPGRADES are items available for aftermarket sales. An upgrade may include and enable functionality which is identified as being "Not available" for the initial production and sale of the same model.

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