



DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC,
and of the directive 2011/65/EU.

We

Manufacturer:
GE Vingmed Ultrasound AS
Strandpromenaden 45,
3191 Horten, Norway

Declare under our sole responsibility that the class IIa device:

Vivid E95, Vivid E90, Vivid E80

Ultrasound system, Imaging, Cardiovascular

Software version: **201**

Ref.: See attached addendum.

GMDN Code: **40763**

UMDNS Code: **17-422**

Classification rule (93/42/EC Annex IX): **10**

To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC, which 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.

This conformity is based on the following elements:

- Information included in the technical documentation, ref Technical File **DOC1605870**, of the products to which this declaration relates.
- EC certificate: approval of full quality assurance system (annex II w/o (4) of the medical devices directive 93/42 EEC) delivered by TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany (Notified Body 0123), Certificate N° G1 16 03 23782 082, issued on June 09. 2016.

List of harmonized standards applied for CE marking according to Directive 93/42/EEC:
Medical electrical equipment, general requirements for safety, EN 60601-1:2006 + A1:2013
Medical electrical equipment, part. requirements for ultrasonic equipm, EN 60601-2-37:2008 +A11:2011
Medical electrical equipment, collateral standard, EN 60601-1-2:2007 +AC:2010
Medical electrical equipment, collateral standard, EN 60601-1-6:2010
Medical devices, application of usability engineering to medical devices, EN 62366:2008
Medical Device Software, Software lifecycle process, EN 62304:2006 +AC:2008
Information supplied by the manufacturer of medical devices, EN 1041:2008
Symbols for use in the labeling of medical devices, EN ISO 15223-1:2016

Horten, January 22. 2018


Jan Tore Thollefsen
Regulatory Affairs Manager

This EC declaration of conformity for Vivid E95, Vivid E90 and Vivid E80, replaces the previous dated 23. November 2017.



**ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated January 22, 2018
Vivid E95, Vivid E90, Vivid E80 (v201) – Product, options list and I/O**

CONSOLE Name / with description	GE Vingmed Part # ^[1]	GEMS Cat # ^[2]
Vivid E95	GC000220	H45581DA
Vivid E90	GC000235	H45581LB
Vivid E80	GC000240	H45581DC

OPTIONS CONSOLS	GEMS Cat # ^[2]	Vivid E95	Vivid E90	Vivid E80
Vascular Contrast	H45561MZ	O	O	O
Adv. Contrast Imaging	H45571GY	O	O	O
AFI Productivity Package	H45561GX	O	O	O
IMT	H45561GY	O	O	O
LV Mass Only	H45561NA	O	-	-
4D Strain and LV Mass	H45561NB	O	-	-
4D Auto AVQ	H45581CL	O	-	-
Stress	H45561NC	O	O	O
Auto 2D EF	H45561ND	O	O	O
4V Enable	H45561RJ	O	-	-
Advanced Qscan Imaging	H45561RK	O	O	O
MV Assessment (Tomtec)	H45581LT	O	-	-
RV Volume (TomTec)	H45581GH	O	-	-
4D PolarVision, Vivid Exx	H45571HA	O	-	-
Aurora Advanced Bundle	H45581EF	O	O	O
TEE Interface Module	H45571FK	X	X	O
Quantitative Analysis Package	H45571FL	X	X	O
Tissue Tracking	H45571FM	X	X	O
MPEGVue and eVue	H45571FN	X	X	O
Scan Assist Pro	H45571FP	X	X	O
DICOM Connectivity Package	H45571FR	X	X	O
HDlive	H45581EG	O	-	-
AFI Stress	H45581EH	O	O	O
DICOM viewer	H45581EJ	O	O	O
6VT biplane/triplane option	H45581EK	X	O	-

I/O ^[3]	GEMS Cat # ^[2]	Vivid E95	Vivid E90	Vivid E80
ECG cable, adult, AHA	H45571PY	X	X	X
ECG lead set, adult, AHA	H45571PZ	X	X	X
ECG cable, adult, IEC	H45571RA	X	X	X
ECG lead set, adult, IEC	H45571RB	X	X	X
ECG Cable set	H45521AL	X	X	X
ECG cable, neo, AHA	H45571RD	X	X	X
ECG cable, neo, IEC	H45571RE	X	X	X
Lead/electr neo AHA 600	H45571RJ	X	X	X
Lead/electr neo IEC 600	H45571RK	X	X	X
Adapter, ECG 3-lead	H45571RL	X	X	X

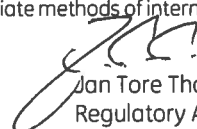
Legend used :

- X Available as standard with this Ultrasound Console
- O Optionally available with this Ultrasound Console
- Not available with this Ultrasound Console.

Notes used in the table :

1. GE Vingmed Part # identifies the device(s) in the manufacturer's design, manufacturing and service documentation. It is usually affixed to the device(s) in the form of a product identification or rating label.
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-devices 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, and included relevant information to users with the Vivid E95/E90/E80 instructions for use. This activity was subject to appropriate methods of internal control and inspection.

Horten, January 22, 2018


 Jan Tore Thollefsen
 Regulatory Affairs Manager



Vivid E95, Vivid E90, Vivid E80 (v201) – Probes with accessories

PROBES w. Accessories ^[3]	TYPE ^[4]	GEHC Cat # ^[2]	Vivid E95	Vivid E90	Vivid E80
4V-D	BF	H40018T	0	-	-
M5Sc-D	BF	H44901AE	0	0	0
6S-D	BF	H45021RR	0	0	0
12S-D	CF	H45021RT	0	0	0
9L-D	BF	H40442LM	0	0	0
11L-D	BF	H40432LN	0	0	0
C1-6-D	BF	H40472LT	0	0	0
C2-9-D	BF	H40462LN	0	0	0
8C	BF	H40412LJ	0	0	0
iC5-9-D	BF	H40442LK	0	0	0
L8-18i-D	BF	H40452LL	0	0	0
6Tc	BF	H455512D	0	0	0
6Tc-RS ^[5]	BF	H455512E	0	0	0
6VT-D	BF	H45581BJ	0	0	0
9T	BF	H45521DY	0	0	0
9T-RS ^[5]	BF	H45531YM	0	0	0
P2D	BF	H4830JE	0	0	0
P6D	BF	H4830JG	0	0	0
TEE Cleaning and Storing System	N/A	H45551NK	0	0	0
TEE Storage Rack	N/A	H45551NM	0	0	0
TEE PROBE ADAPTER FOR 6T-RS/9T-RS	N/A	H45541PX	0	0	0
TEE Scanhead Protection Cover	N/A	H45521CK	0	0	0
Scanhead protection, adult, 25pcs	N/A	H45551MS	0	0	0
Ped TEE Scanhead Protection Cover	N/A	H45541RN	0	0	0
Scanhead protection, pediatric, 25pcs	N/A	H45551MT	0	0	0
TEE Clip-On Bite Guard Adult	N/A	H45511EE	0	0	0
Clip-On Bite Guard, 25pcs	N/A	H45551MM	0	0	0
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB	0	0	0
Clip-On Bite Guard OR, 25pcs	N/A	H45551MN	0	0	0
TEE Conventional Bite Guard Adult	N/A	H45521JH	0	0	0
Bite Guard adult, 25pcs	N/A	H45551MR	0	0	0
TEE Conventional Bite Guard Ped.	N/A	H45521JG	0	0	0
Bite Guard pediatric, 25pcs	N/A	H45551MP	0	0	0
Bite Hole Indicator	N/A	H45531HS	0	0	0
Multiangle replacement kit (x24)	N/A	E8385RC	0	0	0
C1-6-D Biopsy bracket	N/A	H4913BB	0	0	0
C2-9-D Biopsy bracket	N/A	H4913BA	0	0	0
iC5-9-D Needle guide	N/A	E8385MJ	0	0	0
9L Bio guide starter kit	N/A	H4906BK	0	0	0
12L-RS / 11L-D Multi biopsy guide	N/A	H40432LC	0	0	0
M5Sc-D Biopsy kit	N/A	H45561FC	0	0	0

Legend used :

- X Available as standard with this Ultrasound Console
- 0 Optionally available with this Ultrasound Console
- Not available with this Ultrasound Console

Notes :

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. 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, and included relevant information to users with the Vivid E95/E90/E80 instructions for use. This activity was subject to appropriate methods of internal control and inspection.
4. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.
5. 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.

Horten, January 22, 2018


 Jan Tore Thollefsen
 Regulatory Affairs Manager

**Vivid E95, Vivid E90, Vivid E80 (v201)- Accessories and Upgrades**

ACCESSORIES ⁽³⁾	GEHC Cat # ⁽²⁾	Vivid E95	Vivid E90	Vivid E80
Tripedal footswitch	H46732LF	O	O	O
B&W printer, digital with USB	H45531HK	O	O	O
Color Laser Printer 220V	H45541MJ	O	O	O
Color Video Printer	H45561AA	O	O	O
USB Memory Key 32GB	H45581NA	O	O	O
External USB hard disk, 2TB	H45571YW	O	O	O
External Digital Video Stream Recorder	H45581EL	O	O	O
Protective Cover Vivid Expert	H45551NJ	O	O	O
Stereo Glasses for 3D visualization, Set	H45551MH	X	O	-
Spectacle Casing	H45551MJ	O	O	O
Anacrome 3D glasses	H45551MK	X	O	-
Anacrome 3D glasses Clip-On Flips	H45551ML	X	O	-
RealD 038 3D Glasses	H45571YR	O	O	-
RealD 04 Clip-on 3D Glass	H45571YS	O	O	-
Sony 3D monitor kit	H45581AT	O	-	-
Optical Isolation cable	H45571SA	O	O	O
Vivid Exx DVD Option	H45581NB	O	O	O

UPGRADES ⁽⁴⁾	GEHC Cat # ⁽²⁾	Vivid E95	Vivid E90	Vivid E80
Vivid E90 4D upgrade	H45581EM	-	O	-
Vivid E80 4D upgrade	H45581NY	-	-	O

Legend used:

- X Available as standard with this Ultrasound Console
- O Optionally available with this Ultrasound Console
- Not available with this Ultrasound Console

Notes :

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. 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, and included relevant information to users with the Vivid E95/E90/E80 instructions for use. This activity was subject to appropriate methods of internal control and inspection.
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.

Horten, January 22, 2018



Jan Tore Thollefsen
Regulatory Affairs Manager