GE Healthcare

Manufacturer's Authorization

Date: ***18.12.2019***
Procurement number: ***21015181***

To : USMF «Nicolae Testemitanu» university"

WHEREAS

We, **GE Vingmed Ultrasound A/S,** a company duly existing under the laws of Norway, having a registered office and factories at Strandpromenaden 45, 3191 Horten, Norway, with commercial name GE Healthcare, established and reputable manufacturers of Diagnostic Ultrasound Imaging equipment, do hereby authorize ***Intermed SRL,*** our authorized distributor and service provider in the Republic of Moldova, with registered office at *65, Tighina street, office 618, MD-2001 Chisinau*, to submit a bid for the purpose of which is to provide the following Goods, manufactured by us :

VIVID E95 ultrasound system

and to subsequently negotiate and sign the Contract.

On behalf and for **GE Vingmed Ultrasound A/S,**

GE Vingmed Ultrasound

Signed: Véronique Soltani
Name: *Véronique Soltani*
Title: *Tender & Offer Leader – Shared Services Europe*

Dated on 9th day of December, 2019

GE Vingmed Ultrasound A/S
Strandpromenaden 45
3191 Horten, Norway

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 16 03 23782 082

Manufacturer:

GE Vingmed Ultrasound A/S
Strandpromenaden 45
3191 Horten
NORWAY

Facility(ies):

GE Vingmed Ultrasound A/S
Strandpromenaden 45, 3191 Horten, NORWAY

Product Category(ies):

Diagnostic Ultrasound Systems, related Ultrasound Probes and Standalone Software for Ultrasound-Image Processing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713080867

Valid from: 2016-09-02
Valid until: 2021-09-01

Date, 2016-06-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 04.11

GE Healthcare

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

DOC1605874

GE Healthcare

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	H4001BT	O	-	-
M5Sc-D	BF	H44901AE	O	O	O
6S-D	BF	H45021RR	O	O	O
12S-D	CF	H45021RT	O	O	O
9L-D	BF	H40442LM	O	O	O
11L-D	BF	H40432LN	O	O	O
C1-6-D	BF	H40472LT	O	O	O
C2-9-D	BF	H40462LN	O	O	O
8C	BF	H40412LJ	O	O	O
iC5-9-D	BF	H40442LK	O	O	O
L8-18i-D	BF	H40452LL	O	O	O
6Tc	BF	H45551ZD	O	O	O
6Tc-RS [5]	BF	H45551ZE	O	O	O
6VT-D	BF	H45581BJ	O	O	O
9T	BF	H45521DY	O	O	O
9T-RS [5]	BF	H45531YM	O	O	O
P2D	BF	H4830JE	O	O	O
P6D	BF	H4830JG	O	O	O
TEE Cleaning and Storing System	N/A	H45551NK	O	O	O
TEE Storage Rack	N/A	H45551NM	O	O	O
TEE PROBE ADAPTER FOR 6T-RS/9T-RS	N/A	H45541PX	O	O	O
TEE Scanhead Protection Cover	N/A	H45521CK	O	O	O
Scanhead protection, adult, 25pcs	N/A	H45551MS	O	O	O
Ped TEE Scanhead Protection Cover	N/A	H45541RN	O	O	O
Scanhead protection, pediatric, 25pcs	N/A	H45551MT	O	O	O
TEE Clip-On Bite Guard Adult	N/A	H45511EE	O	O	O
Clip-On Bite Guard, 25pcs	N/A	H45551MM	O	O	O
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB	O	O	O
Clip-On Bite Guard OR, 25pcs	N/A	H45551MN	O	O	O
TEE Conventional Bite Guard Adult	N/A	H45521JH	O	O	O
Bite Guard adult, 25pcs	N/A	H45551MR	O	O	O
TEE Conventional Bite Guard Ped.	N/A	H45521JG	O	O	O
Bite Guard pediatric, 25pcs	N/A	H45551MP	O	O	O
Bite Hole Indicator	N/A	H45531HS	O	O	O
Multiangle replacement kit (x24)	N/A	E8385RC	O	O	O
C1-6-D Biopsy bracket	N/A	H4913BB	O	O	O
C2-9-D Biopsy bracket	N/A	H4913BA	O	O	O
iC5-9-D Needle guide	N/A	E8385MJ	O	O	O
9L Bio guide starter kit	N/A	H4906BK	O	O	O
12L-RS / 11L-D Multi biopsy guide	N/A	H40432LC	O	O	O
M5Sc-D Biopsy kit	N/A	H45561FC	O	O	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. 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

DOC1605874

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

DOC1605874

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 023782 0111 Rev. 00

Holder of Certificate: **GE Vingmed Ultrasound A/S**
Strandpromenaden 45
3191 Horten
NORWAY

Facility(ies): GE Vingmed Ultrasound A/S
Strandpromenaden 45, 3191 Horten, NORWAY

Certification Mark:

TÜV SÜD
DIN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production of Diagnostic Ultrasound Systems, related Ultrasound Probes and Standalone Software for Ultrasoundimage Processing and Review Stations**

Applied Standard(s): EN ISO 13485:2016
Medical Devices - Quality Management Systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713126985

Valid from: 2019-01-01
Valid until: 2021-12-31

Date, 2018-10-10

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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GE Healthcare

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II, and of the radio equipment directive 2014/53/EU, annex II, and of the RoHS 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: **203**
Ref.: See attached addendum.

GMDN Code: **40763**

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 and Directive 2014/53/EU.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical documentation, ref Technical File **DOC1605870**, of the product 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.
  - 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 + A1:2015
    Medical electrical equipment, collateral standard, EN 60601-1-2:2015
    Medical electrical equipment, collateral standard, EN 60601-1-6:2010 + A1:2015
    Medical devices, application of usability engineering to medical devices, EN 62366:2008 + A1:2015
    Medical Device Software, Software lifecycle process, EN 62304:2006 + A1:2015
    Information supplied by the manufacturer of medical devices, EN 1041:2008 + A1:2013
    Symbols for use in the labeling of medical devices, EN ISO 15223-1:2016

Horten, March 06, 2019

Jan Tore Thollefsen
Sr. Regulatory Affairs Manager

This EC declaration of conformity supersedes the previous declaration for Vivid E95, Vivid E90, Vivid E80 version v203, dated January 04, 2019.

- For the directive 2011/65/EU (RoHS)
  - Technical documentation, ref Technical File **DOC1605870**, of the product to which this declaration relates.
- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical documentation, ref Technical File **DOC1605870**, of the product to which this declaration relates.
  - Harmonized standards applied on the product to which this declaration relates:
    Health & Safety (Directive 2014/53/EU Art. 3(1)(a)): EN 60601 1:2006 + A1:2013 per Directive 93/42/EEC;
    EMC (Directive 2014/53/EU Art. 3(1)(b)): EN 60601-1-2:2015 per Directive 93/42/EEC;
    Radio Spectrum (Directive 2014/53/EU Art. 3(2)): EN 300 328 v2.1.1 (2016-11); EN 301 893 v1.8.1 (2015-03) + EN 301 893 v2.1.1 (clause 4.2.8 only)–as declared in DOC2039913.

Horten, March 06, 2019

Jan Tore Thollefsen
Sr. Regulatory Affairs Manager

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated March 06, 2019
Vivid E95, Vivid E90, Vivid E80 (v203) – Products, options list and I/O

CONSOLE Name / with description	GE Vingmed Part # [1]	GEMS Cat # [2]
Vivid E95 / v203 with OLED	GC000700-1	H45601ED
Vivid E95 / v203 with LCD	GC000700	H45601EA
Vivid E90 / v203 with OLED	GC000710-1	H45601EF
Vivid E90 / v203 with LCD	GC000710	H45601EB
Vivid E80 / v203 with OLED	GC000720-1	H45601EG
Vivid E80 / v203 with LCD	GC000720	H45601EC
OPTIONS CONSOLS	**GEMS Cat # [2]**	
Vascular Contrast	H45561MZ	
Adv. Contrast Imaging	H45571GY	
IMT	H45561GY	
4D Strain and LV Mass	H45561NB	
4D Auto AVQ	H45581CL	
Stress	H45561NC	
Auto 2D EF	H45601GH	
4V Enable	H45561RJ	
4Vc Enable	H45591PA	
Advanced Qscan Imaging	H45561RK	
4D Auto MVQ	H45591AD	
4D Auto RVQ	H45591AE	
4D PolarVision, Vivid Exx	H45571HA	
HDlive	H45581EG	
AFI Stress	H45581EH	
DICOM viewer	H45581EJ	
Blood Speckle Imaging (BSI)	H45591AF	
Myocardial Work	H45591AG	
Vmax option	H45591HY	
CT Fusion	H45601GN	
4D Markers	H45601GP	
4D Auto LAQ	H45601GR	
Tricefy Uplink	H45601GW	

I/O [3]	GEMS 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

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, March 06, 2019

Jan Tore Thollefsen
Sr. Regulatory Affairs Manager

DOC1605874

Vivid E95, Vivid E90, Vivid E80 (v203) – Probes with accessories

PROBES w. Accessories [3]	TYPE [4]	GEHC Cat # [2]
4V-D	BF	H4001BT
4Vc-D	BF	H40482LS
M5Sc-D	BF	H44901AE
6S-D	BF	H45021RR
12S-D	CF	H45021RT
9L-D	BF	H40442LM
11L-D	BF	H40432LN
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 [5]	BF	H45551ZE
6VT-D	BF	H45581BJ
9T	BF	H45521DY
9T-RS [5]	BF	H45531YM
10T-D	BF	H44901AH
P2D	BF	H4830JE
P6D	BF	H4830JG
TEE Cleaning and Storing System	N/A	H45551NK
TEE Storage Rack	N/A	H45551NM
TEE PROBE ADAPTER FOR 6T-RS/9T-RS	N/A	H45541PX
TEE Scanhead Protection Cover	N/A	H45521CK
Ped TEE Scanhead Protection Cover	N/A	H45541RN
Scanhead protection, pediatric, 25pcs	N/A	H45551MT
TEE Clip-On Bite Guard Adult	N/A	H45511EE
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB
TEE Conventional Bite Guard Adult	N/A	H45521JH
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 Bio guide starter kit	N/A	H4906BK
12L-RS / 11L-D Multi biopsy guide	N/A	H40432LC
M5Sc-D Biopsy kit	N/A	H45561FC

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, March 06, 2019

Jan Tore Thollefsen
Sr. Regulatory Affairs Manager

DOC1605874

Vivid E95, Vivid E90, Vivid E80 (v203) – Accessories

ACCESSORIES [3]	GEHC Cat # [2]
View-X	H45591AK
B&W printer, digital with USB	H45531HK
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 USB hard disk, 2TB	H45571YW
External Digital Video Stream Recorder	H45581EL
Protective Cover Vivid Expert	H45551NJ
Stereo Glasses for 3D visualization, Set	H45551MH
Spectacle Casing	H45551MJ
Anacrome 3D glasses	H45551MK
Anacrome 3D glasses Clip-On Flips	H45551ML
RealD 038 3D Glasses	H45571YR
RealD 04 Clip-on 3D Glass	H45571YS
Vivid Exx DVD Option	H45581NB
Wireless USB Adapter	H45591HS
Vivid Exx Veterinary Kit	H45581LC
Vet probe Caution Label	H48492AW / H48992LR

UPGRADES [4]	GEHC Cat # [2]
Vivid E80 4D Option	H45581NY
Vivid E90 4D Option	H45581EM
Vivid E80_E90_E95 v201 to v202	H45591AL / H45601KX
R2 Software E series	H45591HT
4D HVR Enabler	H45591HW
GRLY board for 4Vc-D	H45591KD
MVA to 4D Auto MVQ Conversion	H45591AM
RV Volume to 4D Auto RVQ Conversion	H45591AN
Vivid E80_E90_E95 v202 to v203	H45601EE

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, March 06, 2019

Jan Tore Thollefsen
Sr. Regulatory Affairs Manager

DOC1605874

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 03 23782 082

Manufacturer:

GE Vingmed Ultrasound A/S
Strandpromenaden 45
3191 Horten
NORWAY

Facility(ies):

GE Vingmed Ultrasound A/S
Strandpromenaden 45, 3191 Horten, NORWAY

Product Category(ies):

Diagnostic Ultrasound Systems, related Ultrasound Probes and Standalone Software for Ultrasound-Image Processing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713080867

Valid from: 2016-09-02
Valid until: 2021-09-01

Date, 2016-06-09

Stefan Preiß

0405276885321

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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