



## **EC DECLARATION OF CONFORMITY**

(Following the provisions of the medical devices directive 93/42/EEC)

We

Manufacturer  
**GE Vingmed Ultrasound AS**  
**P.o.box 141**  
**3191 Horten, Norway**

Declare under our sole responsibility that the class IIa device:

### **Vivid 7 Dimension / Vivid 7 Pro**

Ultrasound system, Imaging, Cardiovascular

Including system components and accessories – See 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.

This conformity is based on the following elements:

- Information included in the documents:  
Design History File Ref.: **FC050756**, of the product to which this declaration relates.
- EC certificate: approval of full quality assurance system (annex II of the medical devices directive 93/42 EEC) delivered by Nemko (Notified Body 0470), Certificate N° EU0703408
- List of harmonized standards applied for CE marking :  
 Medical electrical equipment, general requirements for safety, EN 60601-1  
 Medical electrical equipment, particular requirements for ultrasonic equipm, EN 60601-2-37  
 Medical electrical equipment, collateral standard, EN 60601-1-2  
 Medical electrical equipment, collateral standard, EN 60601-1-4  
 Medical electrical equipment, collateral standard, EN 60601-1-6  
 Biological evaluation of medical devices, EN ISO 10993-1, with relevant tests  
 Medical Device Software, Software lifecycle process, EN 62304  
 Information supplied by the manufacturer of medical devices, EN 1041  
 Symbols for use in the labeling of medical devices, EN 980  
 Application of risk management to medical devices, EN ISO 14971  
 Quality management systems, EN ISO 13485

Horten, Norway, 29-April-2010

  
 Jan Tore Thollefsen  
 Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated 08. May 2009.

**ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 29-April-2010****Vivid 7 Dimension / Vivid 7 Pro – Product, Upgrade and options list**

CURRENT CONSOLES		
PRODUCT / DESCRIPTION	GE Vingmed Part # <sup>(1)</sup>	GEMS Cat # <sup>(2)</sup>
Vivid 7 Dim. w/ Multi-dim. & Volume, 17" LCD mon., 230 Vac	FD000250	H45551XA
Vivid 7 Dim. w/ Multi-dim. & Volume, 19" LCD mon., 230 Vac	FD000310	H45551LA
Vivid 7 Dim. w/ Multi-dim. & Volume, 21" LCD mon., 230 Vac	FD000140	
Vivid 7 Dim. w/ Multi-dim. & Volume, 17" LCD mon., 100-120 Vac	FD000260	H45551XB
Vivid 7 Dim. w/ Multi-dim. & Volume, 19" LCD mon., 100-120 Vac	FD000320	H45551LB
Vivid 7 Dim. w/ Multi-dim. & Volume, 21" LCD mon., 100-120 Vac	FD000150	
Vivid 7 Dim. w/ Multi-dim. Imaging, 17" LCD mon., 230 Vac	FD000270	H45551XC
Vivid 7 Dim. w/ Multi-dim. Imaging, 19" LCD mon., 230 Vac	FD000330	H45551LC
Vivid 7 Dim. w/ Multi-dim. Imaging, 21" LCD mon., 230 Vac	FD000160	
Vivid 7 Dim. w/ Multi-dim. Imaging, 17" LCD mon., 100-120 Vac	FD000280	H45551XD
Vivid 7 Dim. w/ Multi-dim. Imaging, 19" LCD mon., 100-120 Vac	FD000340	H45551LD
Vivid 7 Dim. w/ Multi-dim. Imaging, 21" LCD mon., 100-120 Vac	FD000170	
Vivid 7 Dim. w/ Volume Ultrasound, 17" LCD mon., 230 Vac	FD000290	H45551XE
Vivid 7 Dim. w/ Volume Ultrasound, 19" LCD mon., 230 Vac	FD000350	H45551LE
Vivid 7 Dim. w/ Volume Ultrasound, 21" LCD mon., 230 Vac	FD000180	
Vivid 7 Dim. w/ Volume Ultrasound, 17" LCD mon., 100-120 Vac	FD000300	H45551XF
Vivid 7 Dim. w/ Volume Ultrasound, 19" LCD mon., 100-120 Vac	FD000360	H45551LF
Vivid 7 Dim. w/ Volume Ultrasound, 21" LCD mon., 100-120 Vac	FD000190	
Vivid 7 Dimension console, 17" LCD mon., 230 Vac	FD000210	H45551XG
Vivid 7 Dimension console, 19" LCD mon., 230 Vac	FD000370	H45551LG
Vivid 7 Dimension console, 21" LCD mon., 230 Vac	FD000010	
Vivid 7 Dimension console, 17" LCD mon., 100-120 Vac	FD000220	H45551XH
Vivid 7 Dimension console, 19" LCD mon., 100-120 Vac	FD000380	H45551LH
Vivid 7 Dimension console, 21" LCD mon., 100-120 Vac	FD000020	
Vivid 7 Pro console, 17" LCD mon., 230 Vac	FD000230	H45551XJ
Vivid 7 Pro console, 19" LCD mon., 230 Vac	FD000390	H45551LJ
Vivid 7 Pro console, 21" LCD mon., 230 Vac	FD000120	
Vivid 7 Pro console, 17" LCD mon., 100-120 Vac	FD000240	H45551XK
Vivid 7 Pro console, 19" LCD mon., 100-120 Vac	FD000400	H45551LK
Vivid 7 Pro console, 21" LCD mon., 100-120 Vac	FD000130	

## Notes:

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. GEMS 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.

## Vivid 7 Dimension / Vivid 7 Pro – Product, Upgrade and options list

Previous versions of the same product <sup>(3)</sup>		
PRODUCT / DESCRIPTION	GE Vingmed Part # <sup>(1)</sup>	GEMS Cat # <sup>(2)</sup>
Vivid 7, 230VAC	FC000030	H45001WA
Vivid 7, 230VAC	FC000200	H45521AB
Vivid 7, 230VAC	FC000310	H45521DA
Vivid 7, 230VAC	FC000410	H45531HE
Vivid 7, 115VAC	FC000699	H45531YA
Vivid 7 Dimension, 230VAC w. 4D	FC000610	H45531NJ
Vivid 7 Dimension, 100-120VAC w. 4D	FC000620	H45531NK
Vivid 7 Dimension, 230VAC	FC000630	H45531NE
Vivid 7 Dimension, 100-120VAC	FC000640	H45531NF
Vivid 7 Dimension, 230VAC	FC000910	H45541FG
Vivid 7 Dimension, 100-120VAC	FC000920	H45541FH
Vivid 7 Dimension, w/ Multi-dim & volume 230VAC	FC000760	H45531YY
Vivid 7 Dimension, w/ Multi-dim & volume 100-120VAC	FC000770	H45531YZ
Vivid 7 Dimension, w/ Multi-dim & volume 230VAC	FC000890	H45541FA
Vivid 7 Dimension, w/ Multi-dim & volume 100-120VAC	FC000900	H45541FB
Vivid 7 Dimension, 230VAC	FC000780	H45531YS
Vivid 7 Dimension, 100-120VAC	FC000790	H45531YT
Vivid 7 Dim. w/ Multi-dim. Imaging, 230 VAC	FC000820	H45531YC
Vivid 7 Dim. w/ Multi-dim. Imaging, 100-120 VAC	FC000830	H45531YD
Vivid 7 Dim. w/ Multi-dim. Imaging, 230 VAC	FC000950	H45541FC
Vivid 7 Dim. w/ Multi-dim. Imaging, 100-120 VAC	FC000960	H45541FD
Vivid 7 Dim. w/ Volume Ultrasound, 230 VAC	FC000840	H45531YQ
Vivid 7 Dim. w/ Volume Ultrasound, 100-120 VAC	FC000850	H45531YR
Vivid 7 Dim. w/ Volume Ultrasound, 230 VAC	FC000970	H45541FE
Vivid 7 Dim. w/ Volume Ultrasound, 100-120 VAC	FC000980	H45541FF
Vivid 7 PRO, 230VAC	FC000180	H45521AD
Vivid 7 PRO, 230VAC	FC000330	H45521DC
Vivid 7 PRO, 230VAC	FC000430	H45531HG
Vivid 7 PRO, 230VAC	FC000650	H45531NG
Vivid 7 PRO, 100-120VAC	FC000660	H45531NH
Vivid 7 PRO, 230VAC	FC000800	H45531YW
Vivid 7 PRO, 100-120VAC	FC000810	H45531YX
Vivid 7 PRO, 230VAC	FC000930	H45541FJ
Vivid 7 PRO, 100-120VAC	FC000940	H45541FK

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2. GEMS 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. Conformity to 93/42/EEC was initially declared in a previous EC Declaration of Conformity, giving traceability to relevant revision of the same Technical File.

## Vivid 7 Dimension / Vivid 7 Pro – Product, Upgrade and options list

UPGRADES		
PRODUCT / DESCRIPTION	GE Vingmed Part # <sup>[1]</sup>	GEMS Cat # <sup>[2]</sup>
Vantage Upgrade, V7 / V7 Pro	FD200132	HC45531CA
Upgrade Assembly BT03 to BT08, RFI only	FD200024	H45551KZ
Upgrade BT04 to BT08 Vivid 7	FD200025	H45551KT
Upgrade BT05 to BT08 Vivid 7	FD200026	H45551KW
Upgrade BT06 to BT08 Vivid 7	FD200027	H45551KX
BT08 Completion to 4D w Multidim. & Volume Imaging	FD200029	H45551KY
PRO to Dimension Upgrade	FD200028	H45551MB

I/O and Accessories <sup>[3]</sup>		
Heart Sound Microphone, PCG MA-300 w. Adapter	FD200036	H45001NE
Pulse Pressure Transducer, PCG TY-306 w. adapter	FD200037	H45001NF
Footswitch 3 Pedals IP68	FB200952	H45531UD
ECG Cables IEC, 412931-002	164L0026	E9002ZC
ECG Cable Multi-link 3-lead ECG Neonatal (AHA)	412944-001	412944-001
ECG Cable Multi-link 3-lead ECG Neonatal (IEC)	412944-002	412944-002
ECG Leadwires IEC, 412682-003	164L0028	E9003CN
ECG Cable set	FC200389	H45521AL
ECG cable with banana-type	38401849	E81130HA
ECG-electrodes, snap-type	91920232	91920232
ECG-electrodes SilverTRACE	2014777-001	2014777-001
ECG cable Marquette IEC, 5 leads	164L0026	H45531YK
ECG Cable adapter Multi-link 5-lead DIN adapter	414370-001	414370-001
ECG Cable adapter Multi-link 3-lead DIN adapter	414371-001	414371-001
Analog VCR PAL, Mitsubishi HS-MD3000E	066E9513	H4840JG
DVD-Recorder, JVC BD-X201ME	FC200934	H45541LF
Printer assembly, Color, UP-D23MD	FC100362	H45531HL
Printer, B/W, Sony UP- D897 / UP-D897MD / UP-D897-SYN	FC100942	H45531HK

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2. GEMS 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 are compatible with other GE ultrasound systems, and bears the CE-mark and Notified Body number corresponding to the EC Declaration under which the products are CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the devices in combination with Vivid 7 series, and included relevant information to users with the Vivid 7 series instructions for use.

## Vivid 7 Dimension / Vivid 7 Pro – Product, Upgrade and options list

OPTIONS CONSOLS		
PRODUCT / DESCRIPTION	GE Vingmed Part # <sup>(1)</sup>	GEMS Cat # <sup>(2)</sup>
Multidim. & Volume Imaging BT08	FD200011	H45551LL
	FD200014	H45551LP
	FD200017	H45551LT
	FD200021	H45551LY
Volume Ultrasound BT08	FD200012	H45551LM
	FD200015	H45551LR
	FD200018	H45551LW
	FD200022	H45551LZ
Multidimensional Imaging BT08	FD200013	H45551LN
	FD200016	H45551LS
	FD200019	H45551LX
	FD200023	H45551MA
4D LV Volume	FD200030	H45551KR
4D LV Volume rev. J.	FD200031	H45551KS
Easy 3D	FD200169	H45551MY
M4S-support & True Speed	FC200696	H45541CU
Blood Flow Imaging	FC200602	H45531NL
Anatomical M-mode	FC200603	H45531NM
eVue	FC200606	H45531NQ
MPEGVue	FC200605	H45531NP
LVO Contrast	FC200607	H45531TA
Advanced Contrast (Research)	FC200608	H45531TB
Vascular / Abdominal Contrast	FC200768	H45541EL
Tissue Velocity Imaging & Tissue Tracking	FC200166	H45521BD
Strain and Strain Rate	FD200163	H45551MX
Advanced Qscan Imaging (Strain Imaging)	FC200163	H45521BB
Advanced Qscan Imaging rev. J	FC200171	H45521BF
EchoPAC 7	FC200838	H45001YS
Rodent Application	FC200317	H45521PB
EchoStress	F8200839	H45001YT
Q Analysis	FC200164	H45521BC
IMT - Intima Media Thickness	FC200693	H45541CW
AFI - Automated Functional Imaging	FC200891	H45541LA
EchoDICOM	F8200849	H45001YW
DICOM Modality WL	FC200344	H45521PD
DICOM Print	FC200345	H45521PE
Stereo Glasses for 3D visualization	FD200123	H45551MH
Spectacle Casing	066E0370	H45551MJ
Anacrome 3D glasses	066E0371	H45551MK
Anacrome 3D glasses Clip-On Flips	066E0372	H45551ML

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## Vivid 7 Dimension / Vivid 7 Pro – Product, Upgrade and options list

PROBES w. accessories <sup>(3) (8)</sup>			
PROBE NAME	TYPE <sup>(4)</sup>	GE Vingmed Part # <sup>(1)</sup>	GEMS Cat # <sup>(2)</sup>
3V	BF	2403680	H4900PC
3S	BF	2252157	H4550SZ
3S (ComfortScan)	BF	2223337	H4701SZ
M3S	BF	2295649	H45011SZ
M4S	BF	5132742	H4000PA
5S	BF	2290750	H4901RA
5S (ComfortScan)	BF	2347469	H40422LA
6S	BF	47236867	H45021RS
7S	BF	2251903	H4000P
7S (ComfortScan)	BF	2347471	H40422LB
10S	BF	2298589	H4901PC
3.5C	BF	2296158 / 2050357	H4901PE
4C	BF	2401359	H4904PC
5C	BF	2294516	H40412LA
8C	BF	2348094	H40412LJ
E8C	BF	2294641	H40412LE
7L	BF	2294521	H40412LF
9L	BF	5149427	H40412LT
10L	BF	2294523	H40412LG
12L	BF	2295377	H40412LH
M7C	BF	2294514	H40412LC
M12L	BF	2294511	H40412LD
6T	BF	KN100022	H45001YD
6T	BF	KN100069	H45531HW
6T	BF	KN100092	H45521DX
6T (-RS) <sup>(7)</sup>	BF	KN100093	H45531MZ
6Tc	BF	KN100105	H45551ZD
6Tc (-RS) <sup>(7)</sup>	BF	KN100104	H45551ZE
8T <sup>(6)</sup>	BF	KN100023	H45001YE
9T	BF	KN100072	H45521DY
9T (-RS) <sup>(7)</sup>	BF	KN100073	H45531YM
6Tv <sup>(5)</sup>	BF	KN100062	H45011AA
PAMPTE <sup>(5)</sup>	BF	KN100006	H4830KK
Adapter, 6Tv/PAMPTE <sup>(5)</sup>	N/A	KZ200476	H45001YF
TEE RS Probe adapter <sup>(7)</sup>	N/A	2147094	H45021KP
	N/A	FD200127	H45541PX
Pencil 2D / P2D	BF	TE100024	H4830JE
Pencil 6D / P6D	BF	TQ100002	H4830JG
i8L	CF	KQ100006	H45511NW
i13L	CF	KW100011	H45511NT
Biopsy starter kit (x5) M7C	N/A	1G09785	E8385RF
Biopsy starter kit (x5) M12L	N/A	1G09786	E8385RG
9L Bio guide starter kit	N/A	N/A	H4906BK
Biopsy starter kit (x5) 10L single angle	N/A	1G09343	E8385MC
Biopsy starter kit (x5) 10L multi angle	N/A	1G01017	E8386RJ
Sterile TEE Kit w. Latex Cover /X 12U	N/A		E83851BC
Biopsy starter kit (x5) 12L	N/A	1G09354	E8385MM
Biopsy starter kit (x5) 3.5C	N/A	1G09346	E8385MG
Biopsy bracket 4C	N/A	5160703	E8385NA
Biopsy starter kit (x5) E8C	N/A	1G09376	E8385MJ
M4S/M3S/3S Biopsy kit	N/A	5160711	E8385MZ
Replacement Biopsy supplies	N/A	1G09367	E8385RC
TEE Clip-On Bite Guard Adult	N/A	KZ200687	H45511EE
TEE Clip-On Bite Guard Adult OR	N/A	KZ200693	H45521CB
TEE Conventional Bite Guard Ped.	N/A	086A0010	H45521JG
TEE Conventional Bite Guard Adult	N/A	086A0016	H45521JH

**Notes:**

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  2. GEMS 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 their accessories are compatible with other GEHC ultrasound systems, and bear the CE-mark and Notified Body number corresponding to the EC Declaration under which they are CE-marked. GE Vingmed Ultrasound AS has verified the mutual compatibility of the devices in combination with Vivid 7 series, and included relevant information to users with the Vivid 7 series instructions for use.
  4. Type identifies the degree of protection against electric shock for each probe, as defined in IEC60601-1, sub clause 2.2.25 and 2.2.26, and as labeled by the manufacturer of the probe.
  5. The probes 6Tv and PAMPTE can only be used on Vivid 7 / Vivid 7 Dimension / Vivid 7 PRO BT04 or previous versions, and when used together with Adapter, 6Tv/PAMPTE. The adapter itself is not an applied part.
  6. 8T is only supported on BT03 or previous versions.
  7. The probes 6T-RS and 9T-RS can only be used on Vivid 7 Dimension / Vivid 7 PRO BT05 or later versions, and when used together with the TEE RS Probe Adapter. The adapter itself is not an applied part.
  8. There may be limitations in the support of probes on different versions and revisions of Vivid 7 consoles. Probes with electronic ID that are not supported will not be enabled by the console, and cannot be used for medical purposes. Please refer to the user manual of your console for a list of which probes that will be enabled.
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