



## **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**

Manufacturing site (s):

**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 class IIa devices:

**Vivid S70N, Vivid S60N**

Ultrasound system, Imaging, Cardiovascular  
Software Version: **204**

Ref.: See attached addendum.


GMDN Code: **40763**

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

Class: **IIa**

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 of the radio equipment.

September 21, 2020

  
Carmel Lehrer  
Regulatory Affairs Specialist

Initial release



This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: **DOC1690013 / DOC2184370** of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II w/o (4) of the directive 93/42 EEC) delivered by TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany (Notified Body 0123) / Certificate N° G1 023782 0112.
  - Harmonized standards applied on the product to which this declaration relates:
    - Medical electrical equipment, general requirements for safety, EN 60601-1:2006 + A1:2013
    - Medical electrical equipment, part. requirements for ultrasonic equipment 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 62366-1:2015
    - Medical Device Software, Software lifecycle process, EN 62304:2006 + A1:2015
    - Information supplied by the manufacturer of medical devices, EN 1041:2008 + A1:2013
    - Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements- EN ISO 15223-1:2016
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: **DOC1690013 / DOC2184370** of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical documentation, ref Technical File **DOC1690013 / DOC2184370**, 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.
- For the commission regulation EU No 207/2012 (eIFU)
  - Technical Documentation/DHF Ref./ réf: **DOC1690013 / DOC2184370** of the product to which this declaration relates

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Regulatory Affairs Specialist

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# ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated September 21, 2020

## Vivid S70N / Vivid S60N – Product, options list and I/O

CONSOLE Name / with description	GEMS Cat # [1]	Ref #		
Vivid S70N v204 CN (manufactured in China)	H45601TP	BC000800		
Vivid S60N v204 CN (manufactured in China)	H45601TQ	BC000810		
Vivid S70N v204 NOR (manufactured in Norway)	H45601TR	FR000800		
Vivid S60N v204 NOR (manufactured in Norway)	H45601TS	FR000810		
OPTIONS CONSOLS	GEMS Cat # [1]	Ref #	Vivid S70N	Vivid S60N
Vivid S SW media v204	H45601ZF	BC100830	X	X
Smart Stress	H45551WK	GA200839	X	X
AI Auto Measure - 2D	H45601YX	BC200832	X	X
AI Auto Measure - Spectrum Recognition	H45601YY	BC200833	X	X
Auto EF 3.0	H45601YK	GC200823	X	X
AFI 3.0	H45601WG	GC200822	X	X
AFI RV	H45601TT	GC200833	X	X
AFI LA	H45601TU	GC200834	X	X
Advanced Qscan imaging	H45561RK	GA200891	X	X
QA	H45561HG	GB200027	X	X
IMT	H45551WL	GA200808	X	X
Advanced Vascular/Abdominal Contrast	H45561MZ	GA200832	X	X
Scan Assist Pro	H45571FP	GB200033	X	X
TEE probe Interface	H45571FK	GB200026	X	X
4D	H45581PG	FR200040	X	-
HD Color	H45601ZG	BC200834	X	-
4D Auto MVQ	H45591AD	GC200532	X	-
4D Auto AVQ	H45581CL	GC200215	X	-
4D Markers	H45601GK	GC200733	X	-
View-X	H45591AK	GC200435, 066E8925	X	-
DICOM Network Connectivity	H45551WW	GB200034	X	X
Embedded DICOM viewer on DVDs	H45581EJ	GC200526	X	X
Tricify connectivity	H45601GW	GC200737	X	X
Streaming	H45601GJ	GC200736	X	X
ICE interface	H45591RE	FR200532	X	X
CartoSound interface	H45591RF	-	X	X
Biplane/Triplane Option	H45581EK	GC200286	-	X
Vivid S eDelivery Enable	H45601YRED	BC200830-FI	X	X

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

Notes used in the table:

**Note 1:** GEHC Cat # identifies the device(s) in the manufacturer's catalogue and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

**Note 2:** 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 S70N and Vivid S60N, and included relevant information to users with the Vivid S60N / S70N instructions for use. This whole activity is subject to appropriate methods of internal control and inspection.

September 21, 2020

  
Carmel Lehrer, Regulatory Affairs Specialist



**ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated September 21, 2020**  
**Vivid S70N / Vivid S60N – Product, options list and I/O continued**

UPGRADES	GEMS Cat # [1]	Ref #	Vivid S70N	Vivid S60N
Vivid S70N_S60N v203 to v204UPG	H45601ZA	FR200845	X	X
PSB old R3 N systems + ML6-15-D	H45601YU	NS5766836-2	X	X
Enable M5Sc	H45611HK	BC200835	-	X
I/O [2]	GEMS Cat # [1]	Ref #	Vivid S70N	Vivid S60N
ECG cable, adult, AHA	H45571PY	164L0025	X	X
ECG lead set, adult, AHA	H45571PZ	164L0027	X	X
ECG cable, adult, IEC	H45571RA	164L0026	X	X
ECG lead set, adult, IEC	H45571RB	164L0028	X	X
ECG cable, neo, AHA	H45571RD	164L0029	X	X
ECG cable, neo, IEC	H45571RE	164L0030	X	X
Lead/electrode neo AHA 600	H45571RJ	5759941	X	X
Lead/electrode neo IEC 600	H45571RK	5760483	X	X
Adapter, ECG 3-lead	H45571RL	5760485	X	X
Ext ECG Cable	H45551WD	R2420410	X	X
ECG cable, adult, AHA	H45601SB	2106305-001	X	X
ECG lead set, adult, AHA	H45601SC	2106390-001	X	X
ECG cable, adult, IEC	H45601SD	2106305-003	X	X
ECG lead set, adult, IEC	H45601SE	2106390-003	X	X
ECG cable, neo, AHA	H45601SF	2106306-001	X	X
ECG cable, neo, IEC	H45601SG	2106306-003	X	X
Lead/electrode neo AHA 600	H45601SH	2106891-001	X	X
Lead/electrode neo IEC 600	H45601SJ	2106892-001	X	X
Adapter, ECG 3-lead	H45601SK	2106403-003	X	X

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Notes used in the table:

**Note 1:** GEHC Cat # identifies the device(s) in the manufacturer's catalogue and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

**Note 2:** 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 S70N and Vivid S60N, and included relevant information to users with the Vivid S60N / S70N instructions for use. This whole activity is subject to appropriate methods of internal control and inspection.

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# ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated September 21, 2020

## Vivid S70N / Vivid S60N – Probes with accessories

PROBES w. Accessories <sup>[2]</sup>	TYPE <sup>[3]</sup>	GEMS Cat # <sup>[1]</sup>	Ref #	Vivid S70N	Vivid S60N
3Sc-RS	BF	H45041DL	47237516	X	X
M5Sc-D	BF	H44901AE	5446812	X	X
6S-D	BF	H45021RR	47236955	X	X
12S-D	BF	H45021RT	47237174	X	X
6VT-D	BF	H45581BJ	KN100120	X	X
6Tc-RS	BF	H45551ZE	KN100106	X	X
9T-RS	BF	H45531YM	KN100122	X	X
10T-D	BF	H44901AH	5772436	X	X
9L-D	BF	H40442LM	5194432	X	X
11L-D	BF	H40432LN	5176269	X	X
C1-6-D	BF	H40472LT	5418916	X	X
C2-9-D	BF	H40462LN	5405253	X	X
C3-10-D	BF	H40482LB	5493011	X	X
C1-5-D	BF	H40452LE	5261135	X	X
IC5-9-D	BF	H40442LK	5194434	X	X
P2D	BF	H4830JE	TE100024	X	X
P6D	BF	H4830JG	TQ100002	X	X
L8-18i-D	BF	H40452LL	5336965	X	X
ML6-15-D	BF	H40452LG	5199103	X	X
M5Sc-D Biopsy kit	N/A	H45561FC	442-180	X	X
3Sc-RS Biopsy Kit	N/A	H46222LC	442-18	X	X
9L-D Biopsy Kit	N/A	H4906BK	442-155	X	X
11L-D Biopsy kit	N/A	H40432LC	442-160	X	X
C1-5-D Biopsy kit	N/A	H40432LE	442-174	X	X
C1-6-D Biopsy kit	N/A	H4913BB	442-213	X	X
C2-9-D Biopsy kit	N/A	H4913BA	442-210	X	X
IC5-9-D Biopsy kit	N/A	E8385MJ	134-125	X	X
ML6-15-D Biopsy kit	N/A	H40432LJ	442-172	X	X
TEE Storage Rack	N/A	H45551NM	KX200272	X	X
TEE Clip-On Bite Guard Adult	N/A	H45511EE	KZ200687	X	X
TEE Clip-On Bite Guard Adult OR	N/A	H45521CB	KZ200693	X	X
TEE Conventional Bite Guard Pediatric	N/A	H45521JG	086A0010	X	X
TEE Conventional Bite Guard Adult	N/A	H45521JH	086A0016	X	X
Adult TEE Scanhead Protection Cover	N/A	H45521CK	KZ307808	X	X
Pediatric TEE Scanhead Protection Cover	N/A	H45541RN	KZ307976	X	X
Bite Hole Indicator	N/A	H45531HS	KZ200800	X	X
PEDOF P6 PROBE HOLDER	N/A	N/A	5409577	X	X
i12L HOLDER	N/A	N/A	5409765	X	X

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

Notes used in the table:

**Note 1:** GEHC Cat # identifies the device(s) in the manufacturer's catalogue and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

**Note 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 S70N and Vivid S60N, and included relevant information to users with the Vivid S60N / S70N instructions for use. This whole activity is subject to appropriate methods of internal control and inspection.

**Note 3:** Type identifies the degree of protection against electric shock for each probe, as labelled on the probe itself.

September 21, 2020

  
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**ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated September 21, 2020****Vivid S70N / Vivid S60N – Probes with accessories continued**

PROBES w. Accessories <sup>[2]</sup>	TYPE <sup>[3]</sup>	GEMS Cat # <sup>[1]</sup>	Ref #	Vivid S70N	Vivid S60N
ICEcord-RS w. Ferrite filter	N/A	H48952AR	5771430	X	X
AcuNav™ G 8F	N/A	-	10135910	X	X
AcuNav™ G 10F	N/A	-	10043342	X	X
SoundStar eco 8FG	N/A	-	M-5723-18 (EU ref no.: 10439236)	X	X
SoundStar eco 10FG	N/A	-	M-5723-16 (EU ref no.: 10439072)	X	X
SoundStar 3D 10F	N/A	-	SNDSTR10G	X	X
Carto® 3	N/A	-	FG-5400-00	X	X

**Vivid S70N / Vivid S60N – Accessories, Language support and country Kits**

ACCESSORIES <sup>[2]</sup>	GEHC Cat # <sup>[1]</sup>	Ref #	Vivid S70N	Vivid S60N
USB B/W video printer v204	H45601YZ	UP-D898MD	X	X
USB B/W printer support v204	H45601ZB	N/A	X	X
DVD RW	H45601ZC	N/A	X	X
USB color video printer	H45561AA	UP-D25MD	X	X
Col Laser Printer 220-240V	H45541MJ	N/A	X	X
Col Laser Printer 100-120V	H45541MH	N/A	X	X
Smart Standby - Battery	H45051AB	5399340-2	X	X
Storage box	H45051AC	N/A	X	X
Tripedal footswitch	H46732LF	3000 G	X	X
Stereo Glasses for 3D visualization, Set	H45551MH	NA	X	-
Spectacle Casing	H45551MJ	NA	X	-
Anachrome 3D glasses	H45551MK	NA	X	-
Anachrome 3D glasses Clip-On Flips	H45551ML	NA	X	-
Wi-Fi kit / Wireless USB Adapter	H45591HS	A6210	X	X
Isolated HDMI converter/splitter	H48982AN	DVP-8211HM	X	X

LANGUAGE SUPPORT and country Kits	GEMS Cat # <sup>[2, 4]</sup>	Ref #	Vivid S70N	Vivid S60N
Country Kits / Destination Sets	H45591xx, H45611xx	NA	X	X
A/N keyboard	H45591xw	NA	X	X
<b>Manuals and Documentation</b>	-			
System manuals	H45611xz	NA	X	X
TEE probes manuals	H45531xz, H45541xz, H45551xz, H45561xz, H45571xz, H45601xz, H45581xz	NA	X	X
10T-D Probes User Manuals	H45601xv	NA	X	X
<b>Power Cords</b>				
Power Cords	H45591xy, H45601xy	NA	X	X

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**Note 3:** Type identifies the degree of protection against electric shock for each probe, as labelled on the probe itself.

**Note 4:** Catalogue number extensions: xx, xz, xy, xw, xv define different languages /countries.

*22/9/20*

September 21, 2020

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