



# EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745, directive 2011/65/EU and directive 2014/53/EU.

We:

Manufacturer	EU Authorized Representative
GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do 13204, Republic of Korea Single Registration Number : KR-MF-000001860	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France SRN: FR-AR-000000344

Declare under our sole responsibility that the device:

**Voluson S10 Expert, Voluson S10, Voluson S8t, Voluson S8, Voluson S6**

Upgrade kit:

Voluson Signature to BT22 UPG

Basic UDI-DI: **8406821BUG00209H8**

Identification number:

Product name	Catalog Number	UDI-DI
Voluson S10 Expert	H43282LA	00195278473042
Voluson S10	H43282LB	00195278473059
Voluson S8t	H43282LC	00195278473066
Voluson S8	H43282LD	00195278473073
Voluson S6	H43282LE	00195278473080

Upgrade kit:

Voluson Signature to BT22 UPG H43222LC 00195278473028

Intended Purpose: The **Voluson S10 Expert, Voluson S10, Voluson S8t, Voluson S8 and Voluson S6** are intended for ultrasound evaluation in the following clinical application: Image Acquisition for diagnostic purposes including measurements on acquired images.

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

EMDN Code: **Z11041**

EMDN Description: Ultrasound Scanners

Class: **IIa**

Classification rule (Annex VIII): **Rule 10**

  
 Jiyeon Park  
 Sr. Regulatory Affairs Leader  
 2021-DEC-17



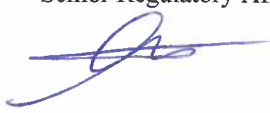
To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and the directive 2014/53/EU on the radio equipment (RED).

This conformity is based on the following elements:

- Technical Documentation reference: DOC2624748, of the product to which this declaration relates.
- EC certificate No. HZ 2004702-01:
  - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
  - Delivered by TUV Rheinland LGA Products GmbH (Notified Body n° 0197)

This EU declaration of conformity supersedes the previous declaration dated 2021-Nov-17.

SIGNATURE:

Date of issue: 2021-Dec-17  
Place of issue: Seongnam-si  
Name: Jiyeon Park  
Function: Senior Regulatory Affairs Leader  
Signature: 



**PHAM HONG SON**  
General Director  
Tổng Giám Đốc



**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2624755**

**Voluson S10 Expert, Voluson S10, Voluson S8t, Voluson S8, Voluson S6  
– Accessories and Components**

Description	Catalog number					
<b>Ultrasound Console &amp; Upgrade kit</b>						
Voluson S10 Expert	H43282LA					
Voluson S10	H43282LB					
Voluson S8t	H43282LC					
Voluson S8	H43282LD					
Voluson S6	H43282LE					
Voluson Signature to BT22 UPG	H43222LC					
<b>Probe with accessories</b>						
Description	Catalog number	Voluson S10 Expert	Voluson S10	Voluson S8t	Voluson S8	Voluson S6
C2-9-RS Probe	H48701WL	1	1	1	1	1
C2-9-D Biopsy Starter Kit	H4913BA	1	1	1	1	1
C1-5-RS Probe	H40462LA	1	1	1	1	1
C1-5 Biopsy Starter Kit	H40432LE	1	1	1	1	1
4C-RS Probe	H4000SR	1	1	1	1	1
4C BIOPSY BRACKET	E8385NA	1	1	1	1	1
8C-RS	H40402LS	1	1	1	1	1
IC9-RS Probe	H48691PJ	1	1	1	1	1
IC9 Biopsy Starter Kit	H48691YW	1	1	1	1	1
IC9 Biopsy Guide	H48691YX	1	1	1	1	1
IC9-RS reusable Biopsy Kit	H48701MN	1	1	1	1	1
IC9B-RS Probe	H48062AK	1	1	1	1	1
E8C REUSABLE BIOPSY KIT	H40412LN	1	1	1	1	1
E721 STARTER KIT	E8385MJ	1	1	1	1	1
E8C E721 E8C-RS IC5-9H MTZ Biopsy Kit	E8333JB	1	1	1	1	1
12L-RS Probe	H40402LY	1	1	1	1	1
12L-RS Biopsy Starter Kit	H40432LC	1	1	1	1	1
9L-RS Probe	H40442LL	1	1	1	1	1
9L BIO GUIDE STARTER KIT	H4906BK	1	1	1	1	1
ML6-15-RS Probe	H40462LM	1	1	1	1	1
ML6-15 Biopsy Starter Kit	H40432LJ	1	1	1	1	1
3Sc-RS Probe	H45041DL	1	1	1	1	1
3SP MULTI-ANGLE BIOPSY	H46222LC	1	1	1	1	1
12S-RS Probe	H44901AB	1	1	1	1	1

*Jijean Park*  
*Sr. Regulatory Affairs Leader*  
*2021 - DEC-17*



RIC5-9A-RS Probe	H48701EJ	1	1	1	1	1
PEC63 BIOPSY KIT FOR RIC5-9	H46721R	1	1	1	1	1
RIC STERILE NEEDLE GUIDE	H48681GF	1	1	1	1	1
RIC STERILE NEEDLE GUIDE	H48691Z	1	1	1	1	1
RAB6-RS PROBE	H48691LP	1	1	1	1	1
RAB6-D BIOPSY STARTER KIT	H48681ML	1	1	1	1	1
<b>Software Options</b>						
3D/4D Activation	H44862LZ	1	1	1	1	1
Advanced 3D/4D Package	H44872LA	1	1	1	1	1
HDlive Silhouette	H44952LY	1	-	-	-	-
Coded contrast imaging	H44962LC	1	1	1	1	1
Radiantflow	H43182LW	1	1	1	1	1
Anatomical M-mode	H44842LC	1	1	1	1	1
Elastography	H44842LD	1	1	1	1	1
Advanced VCI w Omniview	H44842LE	1	1	1	1	1
SonoAVC	H44842LF	1	1	1	1	1
SonoL&D	H44842LG	1	1	1	1	1
SonoVCAD labor	H44842LH	1	1	1	1	1
STIC	H44842LJ	1	1	1	1	1
SonoVCADheart	H44842LK	1	1	1	1	1
TUI	H44842LL	1	1	1	1	1
VOCAL II	H44842LM	1	1	1	1	1
Inversion	H44842LN	1	1	1	1	1
4D biopsy	H44842LP	1	1	1	1	1
SingleView	H44872LE	1	1	1	1	1
HDlive	H44842LR	-	1	1	1	1
DVD and USB Recorder	H43192LB	1	1	1	1	1
Advanced Security Features	H44962LF	1	1	1	1	1
Russian Language Support (RLS)	H44942LT	1	1	1	1	1
4th Probe Port Activation	H44892LD	-	-	1	1	1
3D Print Export	H44962LE	-	-	1	1	1
B-Flow	H44872LS	-	-	1	1	1
XTD	H44872LT	-	-	1	1	1
Scan assistant	H44962LB	-	-	1	1	1
SonoBiometry Brain	H43292LC	1	1	1	1	1
SonoCNS	H43292LD	1	1	1	-	-
Uterine Trace	H43292LE	1	1	1	-	-
C2-9-RS Activation	H43292LB	1	1	1	1	1
4DView 18	H48701YF	1	1	1	1	1
<b>Hardware Options</b>						
VS10 Drawer	H44852LL	1	1	-	-	-

*[Signature]*  
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 2021-DEC-17



S8-S6 High Cabinet	H44892LA	-	-	-	1	1
S8-S6 Drawer	H44892LB	-	-	1	1	1
S8-S6 Gel Holder	H44882LY	-	-	-	1	1
Horizontal TV Holder	H43182LT	-	-	1	-	-
Horizontal TV Holder	H46732LJ	-	-	-	1	1
Vertical TV Holder	H46732LK	-	-	-	1	1
DPS with Battery Pack	H43192LC	1	1	1	1	1
DPS with Battery Pack for MC only	H43192LD	1	1	1	1	1
Battery Pack (LPC only)	H43192LH	1	1	1	1	1
CWD Option Kit	H43192LE	1	1	1	1	1
VS10 Expert - VS10 - VS8t ECG Option Kit	H43192LJ	1	1	1	-	-
VS8 - VS6 ECG Option Kit	H43192LK	-	-	-	1	1
ECG Cable - AHA	H46102LW	1	1	1	1	1
ECG cable - IEC	H46102LZ	1	1	1	1	1
Internal Universal Video Converter	H43192LF	1	1	1	1	1
1TB SSD	H43292LA	1	1	1	1	1
1TB SSD (Make Center Only)	H43292LM	1	1	1	1	1
<b>Peripherals</b>						
B&W Printer Digital (SONY, UP-D898)	H46992LS	1	1	1	1	1
Color Printer Digital (SONY, UP-D25MD)	H44642LW	1	1	1	1	1
B&W Printer install kit, VS10 Expert & VS10	H44962LN	1	1	-	-	-
Color Printer install kit, VS10 Expert & VS10	H44962LK	1	1	-	-	-
BW Printer Kit, VS10 Expert & VS10	H44972LB	1	1	-	-	-
Color Printer Kit, VS10 Expert & VS10	H44962LW	1	1	-	-	-
B&W Printer install kit, VS8t, VS8, VS6	H44962LP	-	-	1	1	1
Color Printer install kit, VS8t, VS8, VS6	H44962LL	-	-	1	1	1
BW Printer Kit, VS8t - VS8	H44972LC	-	-	1	1	1
Color Printer Kit, VS8t - VS8	H44962LY	-	-	1	1	1
Power Cord 220V for EU	H46342LZ	-	-	1	1	1
Network Printer EU	H48701EZ	1	1	1	1	1
Network Printer USA	H48711MZ	1	1	1	1	1
<b>Accessories</b>						
WLAN Stick	H44932LH	1	1	1	1	1
USB FootSwitch - 3 Buttons	H46732LF	1	1	1	1	1
Bar Code Scanner	H48701JH	1	1	1	1	1


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 2021-DEC-17



32" External Patient Monitor Set	H48701WK	1	1	1	1	1
Ethernet Protection Cable	H43272LJ	1	1	1	1	1
Isolation Transformer	H48671WN	1	1	1	1	1
Isolated USB connector	H46972LZ	1	1	1	1	1
Isolated 1Gb Ethernet connection	H46972LY	1	1	1	1	1
System power supply noise filter (EMI filter)	H46162LH	1	1	1	1	1
Universal Power Supply (UPS) 220V/230V	H48691PE	1	1	1	1	1
Power Cord Fix Bracket 220V	H46912LC	1	1	1	1	1
Power Cord Fix Bracket 110V	H46912LD	1	1	1	1	1
Color Print Pack UPC-21 L	H46851B	1	1	1	1	1
Color Print Pack UPC-21 S	H46861B	1	1	1	1	1
High-Glossy BW Printer Paper (UPP-110HG)	H46811A	1	1	1	1	1
Voluson Cleaning Cloth	H43222LZ	1	1	1	1	1
Ocean Pack Material-Korea (only for LPC)	H40242LF	1	1	1	1	1
<b>Upkit</b>						
Voluson S10 BT16 to BT22 UPG	H43222LE	-	1	-	-	-
Voluson S8/S6 BT16 to BT22 UPG	H43222LF	-	-	-	1	1

Note: Probes and accessories may carry the CE-Mark and when applicable, the Notified Body number corresponding to the EC Declaration under with the products are CE marked by their manufacturer. GE Ultrasound Korea, Ltd. has verified the mutual compatibility of the accessories in combination with Voluson S10 Expert, Voluson S10, Voluson S8t, Voluson S8, Voluson S6 and included relevant information to users with the instructions for use.

*End of Document*

  
 Jiyeon Park  
 Sr. Regulatory Affairs Leader  
 2021-DEC-19