

# EC Certificate

EU Quality Management System  
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter 1,  
Section 2 and 3 and Chapter III



Registration No.: HZ 2004702-01

Manufacturer: **GE Ultrasound Korea, Ltd.**  
9, Sunhwan-ro 214beon-gil,  
Jungwon-gu, Seongnam-si, Gyeonggi-do 13204  
Republic of Korea

EUDAMED Single  
Registration No.: No registration number available yet

Products: Class IIa - Z110401 ULTRASOUND SCANNERS

Authorised  
representative(s): GE Medical Systems SCS  
283 Rue de la Minière, 78530 BUC  
France

| Certificate history |                 |             |
|---------------------|-----------------|-------------|
| Revision:           | Description:    | Issue date: |
| 0                   | Initial Version | 2021-01-19  |

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 234155227-40

Effective date: 2021-01-19

Expiry date: 2025-10-09

Issue date: 2021-01-19



TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

## EB Sertifikatas

### EB kokybės užtikrinimo sistema

### Direktyvos (EB) 2017/745 medicinos prietaisams, IX priedo I skyrius,

### 2 ir 3 skirsniai ir III skyrius

Registracijos Nr.: HZ 2004702-01

Gamintojas: **GE Ultrasound Korea, Ltd.**  
9, Sunhwan-ro 214beon-gil,  
Jungwon-gu, Seongnam-si, Gyeonggi-do 13204  
Pietų Korėja

EUDAMED atskiras -

Registracijos Nr. :

Gaminiai: IIa klasės :  
Z110401 - Ultragarso aparatai (skaneriai)

Autorizuoti atstovai: **GE Medical Systems SCS**  
Miniere gatavė 283  
78530 Bukas, Prancūzija

Sertifikato istorija

Revizija: 0 Aprašymas: Pirminė versija

Išleidimo data: 2021-01-19

Notifikuotoji įstaiga pareiškia, kad Direktyvos (EB) 2017/745 reikalavimai medicinos prietaisams, pagal IX priedo I skyrių, 2 ir 3 skirsnius atitinka paminėtiems produktams. Aukščiau nurodytas gamintojas įdiegė ir taiko kokybės užtikrinimo sistemą, kuri yra periodiškai prižiūrima, kaip apibrėžta minėtos direktyvos IX priedo, I skyriaus, 3 skirsnyje. IX skyriaus, III skyriaus reikalavimai yra įvykdyti. Jei III klasės įtaisams arba IIb klasės implantuojamiems įtaisams, nurodytiems 52 straipsnio 4 dalies antroje pastraipoje, taikomas šis sertifikatas tai EB techninių dokumentų įvertinimo sertifikatas pagal II skyriaus 4.9 skirsnį yra būtinas prieš pateikiant juos rinkai.

Išvados Nr. : 234155227-40

/parašas/ Antspaudas: /Sertifikavimo įstaiga TÜV

Įsigaliojimo data: 2021-01-19

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431  
Nürnberg, Vokietija

Galioja iki: 2025-10-09

Išleidimo data: 2021-01-19

## **EU DECLARATION OF CONFORMITY**

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

We:

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

Declare under our sole responsibility that the device:

**Voluson Signature 18, Voluson Signature 20**

Basic UDI-DI: **8406821BUG00309HD**

Identification number:

| Product name         | Part Number / Reference Number | UDI-DI         |
|----------------------|--------------------------------|----------------|
| Voluson Signature 18 | 5928500 / Voluson Signature 18 | 00195278633811 |
| Voluson Signature 20 | 5926010 / Voluson Signature 20 | 00195278633804 |

Intended Purpose: The **Voluson Signature 18, Voluson Signature 20** 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: **Z110401**

EMDN Code: Ultrasound Scanners


Class: **IIa**

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

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: DOC2778720, of the product to which this declaration relates.
- EU certificate No. HZ 2004702-01:
  - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745

  
Jiyeon Park  
Sr. Regulatory Affairs Leader  
2024- Feb - 27

- Delivered by TUV Rheinland LGA Products GmbH (Notified Body n° 0197)

This EU declaration of conformity supersedes the previous declaration dated 2023-Nov-08.

SIGNATURE:

Date of issue: 2024-Feb-27

Place of issue: Seongnam-si

Name: Jiyeon Park

Function: Senior Regulatory Affairs Leader


Signature:



## ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2778721

### Voluson Signature 18, Voluson Signature 20 – Accessories and Components

| Product Description                        | Catalog number |
|--|----------------|
| Voluson Signature 18                       | H43482LF       |
| Voluson Signature 20                       | H43482LE       |
|  |                |
| Description                                | Catalog number |
| <b>Probe with accessories</b>              | -              |
| C1-5 Biopsy Starter Kit                    | H40432LE       |
| C1-5-D Probe                               | H40452LE       |
| C2-9-D Probe                               | H40462LN       |
| C1-6-D Probe                               | H40472LT       |
| C2-9 Biopsy Starter Kit                    | H4913BA        |
| C1-6-D Biopsy Starter Kit                  | H4913BB        |
| E8C REUSABLE BIOPSY KIT                    | H40412LN       |
| E721 STARTER KIT                           | E8385MJ        |
| IC5-9-D Probe                              | H40442LK       |
| 12L-RS Biopsy Starter Kit                  | H40432LC       |
| ML6-15 Biopsy Starter Kit                  | H40432LJ       |
| 11L-D PROBE                                | H40432LN       |
| 9L-D PROBE                                 | H40442LM       |
| ML6-15-D PROBE                             | H40452LG       |
| 9L BIO GUIDE STARTER KIT                   | H4906BK        |
| M5Sc-D PROBE                               | H44901AE       |
| M5S BIOPSY KIT                             | H45561FC       |
| PEC63 BIOPSY KIT FOR RIC5-9                | H46721R        |
| RIC5-9-D PROBE                             | H48651MS       |
| RAB6-D Probe                               | H48681MG       |
| RAB6-D BIOPSY STARTER KIT                  | H48681ML       |
| RIC STERILE Needle Guide                   | H48681GF       |
| RIC STERILE Needle Guide with Latex Cov    | H48691Z        |
| Vscan Air CL C1 Kit with Vscan Air Charger | H45611ZM       |
| Vscan Air CL G1 Kit with Vscan Air Charger | H45611ZN       |
| Vscan Air CL II Kit with Vscan Air Charger | H45611ZP       |
| Vscan Air Activation Kit EU                | H46006BA       |
| <b>Software options</b>                    | -              |
| 3D/4D Package                              | H46006BE       |
| HDlive                                     | H46006BF       |

  
 Jijean Park  
 Sr. Regulatory Affairs Leader  
 2024 Feb-27

|                             |          |
|-----------------------------|----------|
| HDlive Silhouette           | H46006BG |
| Advanced VCI with OmniView  | H46006BH |
| SonoGyn                     | H46006BJ |
| Advanced STIC               | H46006BK |
| SonoAVC                     | H46006BL |
| SonoVCADheart               | H46006BM |
| Inversion                   | H46006BN |
| VOCAL                       | H46006BP |
| Coded Contrast Imaging      | H46006BR |
| Recording Module SW-DVR     | H46006BS |
| Radiantflow                 | H46006BT |
| SlowFlowHD                  | H46006BW |
| SonoPelvicFloor 2.0         | H46006BY |
| SonoCNS                     | H46006BZ |
| SonoLyst                    | H46007BB |
| SonoLystLive                | H46007BC |
| fetalHS                     | H46007BD |
| Elastography                | H46007BE |
| Shearwave Elastography      | H46007BF |
| B-Flow                      | H46007BG |
| XTD                         | H46007BH |
| Scan Assistant              | H46007BJ |
| 4th Probe Port Activation   | H46007BK |
| VscanAir Activation         | H46007BL |
| Ophthalmic Artery           | H46007BM |
| Advanced Security           | H46007BN |
| Premium Security            | H46007BP |
| Voluson Signature eDelivery | H46007BR |
| Voluson Remote Updates      | H46007BS |
| AVURI Device Management     | H46007BT |
| VoiceCommand                | H46007BW |
| Perspective Rendering       | H46008BC |
| Labor & Delivery Package    | H46008BD |
| 4DView 18                   | H48701YF |
| Hardware Options            | -        |
| CW Hardware Option          | H43262LB |
| ECG, external USB           | H43262LJ |
| ECG cable - AHA             | H46102LW |
| Ultrasound ECG cable (IEC)  | H46102LZ |
| Rear Handle Cable Hook      | H46002BA |

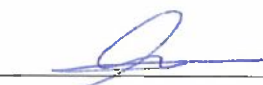
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| Rear Basket  | H46002BC |
| Side Drawer  | H46002BD |
| Rear Tray User Interface                           | H46002BE |
| Gel warmer   | H46002BF |
| Horizontal TV Probe Holder                         | H46002BG |
| Vertical TV Probe Holder Inserts - Right Side      | H46002BH |
| Horizontal IC5-9 TV Probe Holder Insert            | H46002BJ |
| Internal Universal Video Converter (UVC)           | H46002BN |
| Battery Pack                                       | H46002BP |
| Battery Pack, extended                             | H46002BR |
| BW Printer Kit                                     | H46102LS |
| 1 TB SSD for LPC & Field                           | H43262LH |
| 1 TB SSD for Make Center                           | H43272LE |
| CW Hardware Option                                 | H43262LB |
| ECG, external USB                                  | H43262LJ |
| Peripherals  | -        |
| B&W Printer Digital (SONY, UP-D898DC)              | H43272LC |
| Color Printer Digital (SONY, UP-D25MD)             | H44642LW |
| Network Printer EU                                 | H48701EZ |
| Wireless Kit Color Printer                         | H48711KZ |
| Accessories  | -        |
| Wireless Display Solution: EU, UAE                 | H43262LL |
| Wireless Display Solution: ANZ, TWN, SGP, THA, MYS | H43262LS |
| Wireless Display Solution: India                   | H43262LT |
| Ethernet protection cable                          | H43272LJ |
| Bluetooth adapter kit                              | H43502LT |
| Vscan air charger installation kit                 | H46002BK |
| USB WIFI dongle EU installation kit                | H46002BM |
| Pwr supply noise filter                            | H46162LH |
| USB FOOTSWITCH 3 BUTTON                            | H46732LF |
| PWR CORD DK HSP C13 RED                            | H46712LT |
| PWR CORD DK STD C13 GRY                            | H46692LK |
| Power Cord 220V for EU                             | H46342LZ |
| Destination Set - UK                               | H46712LM |
| Destination Set - South Africa                     | H46712LN |
| Destination Set - Israel                           | H46712LR |
| Destination Set - Switzerland                      | H46712LS |
| Destination Set - Australia/New Zealand            | H46712LZ |
| Destination Set - India                            | H46722LB |
| Destination Set - Italy                            | H46722LD |

|   |          |
|---|----------|
| High glossy Paper BW Print                                      | H46811A  |
| PAPER LARGE FOR COLOR PRINTER                                   | H46851B  |
| COLOR PRINT PACK UPC-21 S                                       | H46861B  |
| Isolated USB connector  | H46972LZ |
| ISOLATION TRANSFORMER   | H48671WN |
| UPS 220V-240V   | H48691PE |
| Barcode-Scanner   | H48701JH |
| Ext. Patient Monitor Set  | H48701WK |
| Voluson Cleaning Cloth  | H43222LZ |
| Digital Expert Hardware Kit (includes Microsoft Surface Tablet) | E8390AA  |
| Tablet including Digital Expert and International Kit           | E8390AD  |
| Dig Exp Full Kit 10 Course Int Kit                              | H4920AS  |
| Dig Exp Full Kit 10 Cour  | H4920DS  |

**Note :**

- 1) Catalog number identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sales contract, order processing documents and shipping documents.
- 2) 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 Signature 18, Voluson Signature 20 and included relevant information to users with the instructions for use.

*End of Document*

  
 Jyeon park  
 Sr. Regulatory Affairs Leader  
 2024 - Feb-27