# EC Certificate

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

TÜVRheinland®

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|---|---|
| Registration No.: | HZ 2004702-01 |
| Manufacturer: | **GE Ultrasound Korea, Ltd.**<br>9, Sunhwan-ro 214beon-gil,<br>Jungwon-gu, Seongnam-si, Gyeonggi-do 13204<br>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<br>283 Rue de la Miniere, 78530 BUC<br>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.

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|---|---|
| Report No.: | 234155227-40 |
| Effective date: | 2021-01-19 |
| Expiry date: | 2025-10-09 |
| Issue date: | 2021-01-19 |

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

*Vertimas iš anglų kalbos*

# 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, Gyoenggi-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 TUV

Įsigaliojimo data: 2021-01-19

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

Galioja iki: 2025-10-09

Išleidimo data: 2021-01-19

GE HealthCare

# 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.** | **GE Medical Systems SCS** |
| **9, Sunhwan-ro 214beon-gil,** | **283 rue de la Minière** |
| **Jungwon-gu, Seongnam-si,** | **78530 BUC, France** |
| **GYEONGGI-DO 13204, Republic of Korea** | |
| **Single Registration Number (SRN): KR-MF-000001860** | **SRN: FR-AR-000000344** |

Declare under our sole responsibility that the device:

**LOGIQ Totus**

Basic UDI-DI: **8406821BUG00347HM**

**Identification number:**

| Product Name | Part number/Reference number | UDI-DI(GTIN) |
|---|---|---|
| **LOGIQ Totus** | **5926013 / LOGIQ Totus** | **00195278664600** |
| **LOGIQ Totus** | **5943511 / LOGIQ Totus HDU** | **00195278724342** |

Intended Purpose: The **LOGIQ Totus** is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body fluid.

GMDN Code: **40761**

GMDN Description: **General-Purpose ultrasound imaging system**

EMDN Code: **Z110401**

EMDN Description: **Ultrasound Scanner**

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 of the European Parliament and of the council of 8 June 2011 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: DOC2799036, of the product to which this declaration relates.
- EU certificate No. **HZ2004702-01**:
  - Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
  - Delivered by TUV Rheinland LGA Products GmbH (Notified Body N° 0197)

Chae-Rin, Song
Regulatory Affairs Leader
GE Ultrasound Korea, Ltd.
16-Feb-2024

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

**SIGNATURE:**

| | |
|---|---|
| **Date of issue:** | 2024-Feb-16 |
| **Place of issue:** | Seongnam-si |
| **Name:** | Chae-Rin, Song |
| **Function:** | Regulatory Affairs Leader |
| **Signature:** | Chae-Rin, Song |

GE HealthCare

# ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2827601
## LOGIQ Totus – Accessories and Components

| Product Description | Catalog Number(Hcat#)[2] |
|---|---|
| **Base systems** | |
| LOGIQ Totus | H46202LA |
| LOGIQ Totus(ref. LOGIQ Totus HDU[1]) | H46222LT |
| **Probes** | |
| M5Sc-D | H44901AE |
| 6S-D | H45021RR |
| 12S-D | H45021RT |
| ML6-15-D | H40452LG |
| L3-12-D | H48062AA |
| L6-24-D | H4920HF |
| 9L-D | H40442LM |
| C1-6-D | H40472LT |
| C1-6VN-D | H40472LW |
| C3-10-D | H40482LB |
| C2-7-D | H46422LM |
| C2-7VN-D | H46422LN |
| IC5-9-D | H40422LK |
| RAB6-D | H48681MG |
| RIC5-9-D | H48651MS |
| P2D | H4830JE |
| P6D | H4830JG |
| **Software Options** | |
| Adv. Security | H46003BW |
| Coded Contrast | H46003BY |
| Cardiac AFI (=Cardiac Strain) | H46162LK |
| Report Writer | H46003BZ |
| TVI | H43942LZ |
| Auto EF | H43952LA |
| Stress Echo | H46004BA |
| Trice | H46004BB |
| LOGIQ Apps | H46004BC |
| Scan Assistant | H46004BD |
| AUTO IMT | H46004BE |
| B Steer+ | H46004BF |
| B-FLOW | H46004BG |
| FLOW QA (=Color Quantification, Q-Analysis) | H46004BH |
| Measure Assist Breast | H46004BJ |
| Measure Assist OB | H46004BK |
| ELASTOGRAPHY (=Strain Elastography) | H46004BL |
| ELASTO QA (=Elasto Quantification Analysis) | H46004BM |
| Shear Wave Elastography | H46004BN |
| UGAP | H46004BP |
| Hepatic Assistant - SWE-UGAP | H46004BR |
| Omni View | H46004BS |
| HDlive | H43952LB |
| STIC | H46004BT |
| TUI | H46004BW |
| VCI-Static | H46004BY |
| VOCAL II | H46004BZ |
| SonoNT SonoIT | H46005BA |
| Compare Assistant | H46005BB |





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Regulatory Affairs Leader
GE Ultrasound Korea, Ltd.
16-Feb-2024

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|---|---|
| DESTINATION SET ISRAEL | H46712LR |
| DESTINATION SET SWISS | H46712LS |
| DESTINATION SET DENMARK | H46712LT |
| DESTINATION SET ITALY | H46722LD |
| Power Cord 220V for EU | H46342LZ |
| PWR CORD DK STD C13 GRY | H46692LK |
| PWR SPLY CRD EUROPE KOREA | H48502AW |
| PWR SPLY CRD UK IRELAND | H48512AF |
| PWR SPLY CRD SWITZERLAND | H48512AJ |
| PWR SPLY CRD DENMARK HOSPITAL GRADE | H48532AY |
| **VNAV related option** | |
| Volume Navigation | H46002BW |
| VNav Stand (Offboard) | H4908NS |
| VNav Probe sensors | H4913PS |
| VNav NEEDLE TRACKING | H4910NT |
| VNav VirtuTRAX Starter Kit | H4910NY |
| VNav Virtual Tracker sensor(=OmniTrax Sensor) | H4911NG |
| VNav Needle Tracking storage insert | H4913NS |
| VNav Needle Tracking Kit - 18/20g or less | H4913NT |
| VNav ETRAX 12 14G ST KT | H4913NU |
| VNav ETRAX 14 16G ST KT | H4913NV |
| VNav Active Tracker kit | H4913AT |
| VNav MR Active Tracker | H4915MT |
| **Vscan Air CL Option** | |
| Vscan Air CL C1 Kit (most Europe) | H45611ZM |
| Vscan Air CL G1 Kit (UK, Hongkong) | H45611ZN |
| Vscan Air Holder & Charger | H46003BK |
| **Biopsy Options [3]** | |
| C3-10 VNav Holder Starter Kit | H40482LF |
| IC5-9 V NAV BRACKET | H4908NF |
| 9L Vol Navigation Bracket | H4908NB |
| M5S V NAV BRACKET | H4908NM |
| ML6-15 M_BPSY_TRU3D_SKIT | H40432LK |
| M5Sc-D Biopsy Bracket | H45561FC |
| L3-12-D Biopsy Kit | H48302AA |
| ML6-15 Biopsy Starter Kit | H40432LJ |
| 9L BIO GUIDE STARTER KIT | H4906BK |
| C2-7 Biopsy Kit | H40482LK |
| C2-7 Biopsy Kit Stainless | H40482LL |
| C1-6-D Verza Biopsy Starter Kit | H4917VB |
| C1-6-D Biopsy Starter Kit | H4913BB |
| C1-6-D UP2 Biopsy Kit Software Option | H4921UB |
| IC5-9-D Needle guide | E8385MJ |
| IC5-9-D Reusable Biopsy Guide | H40412LN |
| E8C E721 E8C-RS IC5-9H MTZ Biopsy Kit | E8013AT |
| RAB6-D BIOPSY STARTER KIT | H48681ML |
| RAB BIOPSY STARTER KIT | H46701AE |
| RIC5-9-D Biopsy Guide | H46721R |
| RIC STERILE NEEDLE GUIDE | H48681GF |

Notes:

[1] The only difference between LOGIQ Totus and LOGIQ Totus HDU is monitor. LOGIQ Totus is LCD monitor and LOGIQ Totus HDU is HDU monitor.

[2] 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.





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Regulatory Affairs Leader
GE Ultrasound Korea, Ltd.
16-Feb-2024

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|---|---|
| Thyroid Productivity | H46005BC |
| Breast Productivity | H46005BD |
| Probe check | H46005BE |
| Auto Preset Assistant | H46162LR |
| Auto Abdominal Color Assistant | H46162LW |
| Voice Control | H46162LS |
| Software DVR | H46162LY |
| LOGIQ SRI HD Type 2 | H46162LZ |
| LOGIQ KOIOS 2.x INSTALL | H4919KI |
| Koios Breast Activation for LOGIQ | H4922BA |
| KOIOS 3.x INSTALL | H4921KY |
| Koios Thyroid Activation for LOGIQ | H4922TA |
| DICOM | H46003BT |
| Data Streaming(Data Share) | H46162LM |
| e-Delivery | H43952ED |
| **Hardware Options** | |
| Gel Warmer | H46003BB |
| CW Doppler | H46003BA |
| CW Pencil Probe Connector | H46002BZ |
| Real-Time 4D | H46003BP |
| Battery Pack | H46003BR |
| Battery Pack extended | H46003BS |
| Internal Universal Video Converter | H46003BN |
| **ECG options** | |
| ECG Option | H46002BY |
| ECG CABLE - AHA STYLE | H4910EC |
| FC389, ECG CABLE SET | H45521AL |
| ECG Cables IEC Style | H4911JC |
| Pwr supply noise filter | H46162LH |
| **Peripherals** | |
| **Printers** | |
| SONY UP-D25MD Color PRINTER | H4911JT |
| SONY UP-D25MD Color PRINTER Set | H4911JW |
| SONY UPD898DC BW Printer Kit(H46002BB + H43272LC) | H46102LS |
| BW Printer Install Kit | H46002BB |
| BW Printer, UP-D898DC | H43272LC |
| **Accessories** | |
| WLAN-Bluetooth Combi Dongle | H46003BL |
| WLAN Module | H46003BM |
| USB FOOTSWITCH 3 BUTTON | H46732LF |
| TVTR Probe Holder | H43352LE |
| Small Probe Holder | H46302LB |
| PROBE CABLE HANGER | H44412LA |
| Upper Rear Storage Tray | H46002BT |
| Rear Basket | H46002BC |
| Rear Handle Cable Hook | H46002BA |
| Side Drawer | H46002BS |
| Ultrasound Probe Rack | E8363JF |
| Ethernet Protection Cable | H43272LJ |
| Powervar144k120v MG UPS | H4913UP |
| Powervar144k 230V MG UPS | H4921UP |
| UPS Document kit | H46512LJ |
| Ocean shipment packing material 2 | H40252LY |
| **Power Cords and Destination Sets Options** | |
| DESTINATION SET UK | H46712LM |
| DESTINATION SET S AFRICA | H46712LN |





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16-Feb-2024

[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 Ultrasound Korea Ltd. has verified the mutual compatibility of the devices in combination with LOGIQ Totus and included relevant information to users with the LOGIQ Totus instructions for use.

End of Document

Chae-Rin, Song
Regulatory Affairs Leader
GE Ultrasound Korea, Ltd.
16-Feb-2024