

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 (SRN): 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:

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: **Ila**

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

LOGIQ Totus EU DoC
DOC2827601



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*



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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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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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^[1]	
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.



[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

