



EC DECLARATION OF CONFORMITY

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

We

Manufacturer and manufacturing site	EU Authorized Representative
GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si Gyeonggi-do 13204, Republic of Korea 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 Fortis

Basic UDI-DI: **8406821BUG00214GZ**

Identification number:

REF Catalog	H-Catalog Number	UDI-DI
LOGIQ Fortis HDU	H43302LA	00195278405326
LOGIQ Fortis LCD	H43302LB	00195278405333

Intended Purpose: The LOGIQ Fortis 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 and fluid.

EMDN Code: **Z110401**

EMDN Description: Ultrasound Scanners

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

UMDNS Code: **15-976**

Classification: **Ila**

Classification rule (Annex VIII): **Rule 10, Class: Ila**

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: DOC2379389, 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 EC declaration of conformity is the initial release.

SIGNATURE:

Date of issue: 13-12-2021
Place of issue: China
Name: Qingmeng Chen
Function: Regulatory Affairs Program Manager
Signature:

Qingmeng Chen



ADDENDUM TO THE EC DECLARATION OF CONFORMITY
LOGIQ Fortis including accessories and components
dated 13-12-2021

Product Description	H-Catalog Number ¹
Ultrasound Console	
LOGIQ Fortis HDU Console	H43302LA / 6602000
LOGIQ Fortis LCD Console	H43302LB / 6601000
Probe Options²	
IC5-9-D	H40442LK
ML6-15-D	H40452LG
L8-18i-D	H40452LL
C2-9-D (XDClear)	H40462LN
C1-6-D (XDClear)	H40472LT
C1-6VN-D (XDClear)	H40472LW
C2-9VN-D (XDClear)	H40472LY
C3-10-D (XDClear)	H40482LB
M5Sc-D (XDClear)	H44901AE
L2-9-D	H44901AI
L2-9VN-D	H44901AJ
6Tc-RS	H45551ZE
C2-7-D	H46422LM
C2-7VN-D	H46422LN
P2D	H4830JE
RIC5-9-D	H48651MS
RAB6-D	H48681MG
P6D	H4830JG
BE9CS-D	H40482LE
L3-12-D	H48062AA
6S-D	H45021RR
L6-24-D Probe	H4920HF
TEE Probe Accessories²	
TEE RS-DLP Adapter	H46352LK
Adult TEE Clip-on Bite Guard	H45511EE
Adult TEE Clip-on Bite Guard Opr.	H45521CB
Adult TEE Scanhead Protection Cover	H45521CK
Adult TEE Conventional Bite Guard	H45521JH
BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
Software Options	
Advanced Security	H46622LL
Coded Contrast	H43332LA
Parametric Imaging	H43332LB
Cardiac AFI	H46622LN
LOGIQ Exx DVR	H4918DR
Report Writer	H46622LR
Stress Echo	H46622LS
Tricefy	H46622LT
LOGIQ Apps	H46622LW
KOIOS SW	H46622LY
LOGIQ Exx KOIOS Thyroid	H4920KT
LOGIQ E10 KOIOS INSTALL	H4919KI



Product Description	H-Catalog Number ¹
KOIOS 3.x INSTALL	H4921KY
Scan Assistant	H46622LZ
Advanced Probes	H46612LS
AUTO IMT	H46612LT
B Steer+	H46612LW
B-FLOW	H46612LY
Compare Assistant	H46612LZ
DICOM	H46622LA
FLOW QA	H46622LB
Measure Assist Breast	H46622LC
Measure Assist OB	H46622LD
Elastography	H43332LC
Elasto QA	H43332LD
Shear Wave Elastgraphy	H46622LE
LOGIQ Exx SRI HD Type2	H4920SR
UGAP	H46622LH
SonoNT SonoIT	H46622LJ
LOGIQ Exx VNAV Image	H4920VR
Hepatic Assistant - SWE-UGAP	H43332LE
Omni View	H43332LF
STIC	H43332LG
TUI	H43332LH
VCI-Static	H43332LJ
VOCAL_II	H43332LK
Thyroid Productivity	H43332LL
Breast Productivity	H43332LM
Vita on Demand	H43332LN
Hardware Options²	
CW Doppler	H43342LA
Realtime 4D	H43342LB
ECG Option	H43342LC
Scan on battery option kit	H43342LD
Power Assistant	H43342LE
Volume Navigation	H43342LF
Volume Navigation for V-Nav Inside T1	H43372LK
Wireless Option	H43342LG
S-Video Option	H43342LH
Pencil CW	H43342LJ
Peripheral Options²	
USB FOOTSWITCH 3 BUTTON	H46732LF
SONY UPD25MD COLOR PRINTR	H4911JT
BW Printer Installation Kit T1	H43342LK
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
LOGIQ Fortis High Cabinet	H43342LL
LOGIQ Fortis Low Cabinet	H43342LM
LOGIQ Fortis Side Cabinet	H43342LN
Sinch bay Option	H43342LP
An Keyboard Assembly	
AN Keyboard ENGLISH	H43342LR
AN Keyboard GERMAN	H43342LS
AN Keyboard FRENCH	H43342LT
AN Keyboard GREEK	H43342LW
AN keyboard NORWEGIAN	H43342LY



Product Description	H-Catalog Number ¹
AN Keyboard SWEDISH	H43352LA
Accessories²	
Ethernet protection Cable	H43272LJ
FC389,ECG CABLE SET	H45521AL
VNav Stand (Offboard)	H4908NS
ECG CABLE - AHA STYLE	H4910EC
VNav NEEDLE TRACKING	H4910NT
VNav VirtuTRAX Starter Kit	H4910NY
ECG Cables IEC Style	H4911JC
VNav Virtual Tracker	H4911NG
VNav Active Tracker kit	H4913AT
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 Probe sensors	H4913PS
VNav MR Active Tracker	H4915MT
Small Probe Holder	H43352LC
VERTICAL TV PROBE HOLDER	H43352LD
TVTR Probe Holder	H43352LE
PROBE CABLE HANGER	H44412LA
OPTION TRAY BOX	H43372LF
OPTION TRAY Bracket	H43372LG
Power Cords Destination Sets	
Power Cord 220V for EU	H46342LZ
Power Cord DK STD C13 GRY	H46692LK
DESTINATION SET UK	H46712LM
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION SET ITALY	H46722LD
V-nav Options²	
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
C3-10 VNav Holder Starter Kit	H40482LF
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
M5S V NAV BRACKET	H4908NM
Biopsy Kits²	
E721 STARTER KIT	E8385MJ
IC5-9-D Reusable Biopsy Guide	H40412LN
ML6-15 M_BIOPSY_SKIT	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
L2-9 Needle Guide Starter Kit	H44901AM
M5Sc-D Biopsy Bracket	H45561FC
RAB BIOPSY STARTER KIT	H46701AE
RIC5-9-D Biopsy Guide	H46721R
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
C1-6-D Biopsy Starter Kit	H4913BB
L3-12-D Biopsy Kit	H48302AA
RAB6-D BIOPSY STARTER KIT	H48681ML
BE9CS Biopsy Kit 742-401	H42742LJ



Notes:

[1] *H-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 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 Fortis and included relevant information to users with the LOGIQ Fortis instructions for use.*

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