



## **EU DECLARATION OF CONFORMITY**

Following the provisions of the medical devices regulation 2017/745.

We:

### **Manufacturer**

GE Medical Systems Ultrasound and Primary Care  
Diagnostics, LLC.  
9900 Innovation Drive  
Wauwatosa, WI 53226  
Single Registration Number (SRN):PENDING

### **EU Authorized Representative**

GE Medical Systems SCS  
283 rue de la Minière  
78530 BUC, France  
SRN: FR-AR-000000344

### **Manufacturing Site**

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.  
9900 Innovation Drive  
Wauwatosa, WI 53226

GE Ultrasound Korea, Ltd.  
9, Sunhwan-ro 214beon-gil,  
Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Declare under our sole responsibility that the device:

LOGIQ E10

Basic UDI-DI: 8406821BUG00028H2

Identification number: 00195278384041

Intended Purpose: Ultrasound imaging of anatomical structures and blood flow.

GMDN Code: 40761

GMDN Description: General-purpose ultrasound imaging system

EMDN Code: Z11041

EMDN Description: Ultrasound Scanners

GMDN Description: Ultrasound system, imaging, general-purpose

Class: IIa

Classification rule (Annex VIII): RULE 10 OF ANNEX VIII OF COUNCIL REGULATION EU 2017/745

Upgrade Kits: R1 to R3 Upgrade (DI-00195278394101); R2 to R3 Upgrade (DI-00195278394088)

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: DOC2464446 of the product to which this declaration relates.
- EC certificate No.: HZ 2237176-1
  - Conformity assessment procedure followed: Annex IX excluding Chapter I, Section 2 and 3 and Chapter III
  - Delivered by TUV RHeinland 0197

SIGNATURE:

Date of issue: 19-Nov-21  
Place of issue: Wauwatosa, WI USA  
Name: Elizabeth Wentworth  
Function: Regulatory Affairs Leader  
Signature:

*Elizabeth Wentworth*





## ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2464449

## LOGIQ E10 – Accessories and Components

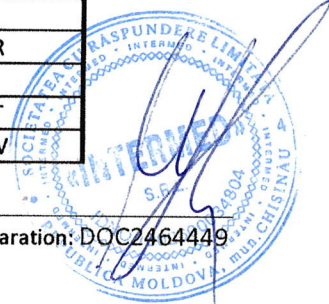
Product Description	Catalogue Designation <sup>1</sup>
LOGIQ E10 R3 HDU Console	H4921Z
LOGIQ E10 R3 HDU CW Capable Console	H4921ZA
LOGIQ E10 R3 OLED Console	H4921ZP
LOGIQ E10 R3 OLED CW Capable Console	H4921ZQ
LOGIQ E10 R3 HDU Console (GEUK)	H4921ZZ
LOGIQ E10 R3 HDU CW Capable Console (GEUK)	H4921ZY
LOGIQ E10 R3 OLED Console (GEUK)	H4921ZX
LOGIQ E10 R3 OLED CW Capable Console (GEUK)	H4921ZW
Software Version	R3.X.X
R1 to R3 Upgrade	H4921YA
R2 to R3 Upgrade	H4921YB
<b>Compatible Ultrasound Probes<sup>[2]</sup>:</b>	
IC5-9-D Probe	H40442LK
ML6-15-D PROBE	H40452LG
L8-18I-D Probe	H40452LL
C2-9-D Probe	H40462LN
C1-6-D Probe	H40472LT
C1-6VN-D Probe	H40472LW
C2-9VN-D Probe	H40472LY
C3-10-D Probe	H40482LB
BE9CS-D Probe	H40482LE
M5Sc-D PROBE	H44901AE





L2-9-D Probe	H44901AI
L2-9VN-D probe	H44901AJ
6S-D PROBE	H45021RR
6Tc-RS Probe	H45551ZE
C2-6b-D probe	H46332LW
C2-7-D Probe	H46422LM
C2-7VN-D Probe	H46422LN
L3-12-D Probe	H48062AA
P2D Probe	H4830JE
P6D Probe	H4830JG
RIC5-9-D PROBE	H48651MS
RAB6-D Probe	H48681MG
L3-9i-D Transducer	H4915IO
L6-24-D Probe	H4920HF
ML4-20-D Probe	H44901AT
ML4-20VN-D Probe	H44901AU

SW & Hardware Options	Catalog Designation <sup>1</sup>
LOGIQ Exx Adv. Security	H4918AS
LOGIQ Exx Coded Contrast	H4918CC
LOGIQ Exx Cardiac AFI	H4918CS
LOGIQ Exx DVR	H4918DR
LOGIQ Exx Report Writer	H4918RW
LOGIQ Exx Stress Echo	H4918SE
LOGIQ Exx Trice	H4918T
LOGIQ Exx LOGIQ Apps	H4918TA
LOGIQ E10 KOIOS SW	H4919KO
LOGIQ Exx KOIOS Thyroid	H4920KT
LOGIQ Exx Scan Assistant	H4919SA
Hepatic Assistant – SWE-UGAP	H43332LE
LOGIQ Exx Contrast SH	H4920CI
LOGIQ Exx Micro B-flow	H4920MB
Vita on Demand	H43332LN
LOGIQ Exx Raw Data Capture	H4920RC
LOGIQ Exx SRI HD Type 2	H4920SR
LOGIQ Exx Sono T	H4920ST
LOGIQ Exx UGAP	H4920U
LOGIQ Exx VNAV Image	H4920VR
LOGIQ Exx Bin - Large	H4918B
LOGIQ Exx Bin - Twin	H4918BT
LOGIQ Exx CW Doppler	H4918CW





LOGIQ Exx Realtime 4D	H4918D
LOGIQ Exx ECG	H4918EG
LOGIQ Exx Power Assistant	H4918PA
LOGIQ Exx Shearwave	H4918SW
LOGIQ Exx Volume Nav	H4918VN
LOGIQ Exx Wireless	H4918WL
LOGIQ E10 CW Field	H4919CW
LOGIQ Exx CW Field	H4920CW
LOGIQ E10 Scan Converter	H4920SC
CW Doppler for LOGIQ Exx	H4921C
LOGIQ Exx Wireless	H4920WL
CW Doppler for LOGIQ Exx - Includes CRX	H4921CW

Accessories <sup>[9]</sup>	Catalog Designation <sup>1</sup>
USB FOOTSWITCH 3 BUTTON	H46732LF
STD ALONE INT UPD25 W ACC	H4911JW
Powervar144k120v MG UPS	H4913UP
LOGIQ Exx Onboard Printer	H4918BW
LOGIQ Exx Protective Cover	H4918DC
LOGIQ Exx Inkjet Printer	H4918RP
LOGIQ Exx Second Monitor	H4918SM
Barcode Reader USBee1000A	Z72692FB
230V UPS Option	H4921UP
Magnetic Card Reader	Z72212FB
Ultrasound Probe Rack	E8363JF
Microsoft Surface Tablet with Case	E8390AB
FC389, ECG CABLE SET	H45521AL
8 oz Ultrasound Gel	H48492AT
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





LE9 Probe Holder Insert 2	H4915P
KOIOS 2.x INSTALL	H4919KI
LExx Tablet	H4920BD
USB barcode reader Honeywell for LE	H48542AE
USB barcode reader Honeywell for Nezha	H48542AF
Dig Exp No Tablet 10 Cour	H4920GS
KOIOS 3.x INSTALL	H4921KY
LOGIQ Exx Protective Cover	H4918DC
TEE RS-DLP Adapter	H46352LK
KZ200687 BITE GUARD	H45511EE
KZ693 BITE GUARD OPR.CLIP ON	H45521CB
KZ808 TEE SCANH. PROTECT.COVER	H45521CK
086A0016 BITE GUARD AD.16*27MM	H45521JH
KZ800,BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
C3-10 VNav Holder Starter Kit	H40482LF
C2-9b-D VNAV Bracket	H46332LZ
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
M5Sc-D VNAV bracket	H4908NM
iC5-9-D Needle guide	E8385MJ
Sterile Disposable Biopsy Needle Guide Kit for GE BE9C Probe	E8387M
Reusable Biopsy Needle Guide for GE BE9C Ultrasound Probe	E8387MA
Reusable Biopsy Needle Guide Starter Kit for GE BE9C Probe	E8387MB
IC5-9-D Reusable Biopsy Guide	H40412LN
ML6-15 M_BIOPSY_SKIT	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
BE9CS Biopsy Kit 742-339	H42742LH
BE9CS Biopsy Kit 742-401	H42742LJ
L2-9 Needle Guide Starter Kit	H44901AM
M5Sc-D Biopsy Bracket	H45561FC
C2-6b Needle Guide Pack	H46332LY
RAB BIOPSY STARTER KIT	H46701AE
RIC5-9-D Biopsy Guide	H46721R
L3-12-D Biopsy Kit	H48302AA
PEC74 BIOPSY KIT FOR RAB LIGHT	H48621Y
RIC Probe Disposable Biopsy Guide - w/o latex covers	H48681GF





RAB6-D BIOPSY STARTER KIT	H48681ML
RIC Probe Disposable Biopsy Guide - w latex covers	H48691Z
C2-9 Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
Ultra-Pro II needle guide	Z73012FB
Ultra-Pro II biopsy bracket	H4921UB
C1-6-D Biopsy Starter Kit	H4913BB
C1-6 Multi Angle Biopsy Set	H78532PA
ML4-20 Verza Starter Kit	H44901AV
Power Cord 220V for EU	H46342LZ

Notes: [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 which the products are CE-marked by their manufacturer. GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC has verified the mutual compatibility of the devices in combination with LOGIQ E10 and included relevant information to users with the LOGIQ E10 instructions for use.

[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 Medical Systems Ultrasound and Primary Care Diagnostics, LLC has verified the mutual compatibility of the devices in combination with LOGIQ E10 and included relevant information to users with the LOGIQ E10 instructions for use.

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