

# **DECLARATION OF CONFORMITY**

Following the provisions of the medical devices directive 93/42/EEC, Annex II  
and of the directive 2011/65/EU and Directive 2014/53/EU on Radio Equipment

We

Manufacturer

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

EU Authorized Representative

**GE Medical Systems SCS  
283 rue de la Minière  
78530 BUC, France**

Manufacturing Sites

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

**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**

Diagnostic Ultrasound System

Ref: see addendum

GMDN Code: **40761** UDI-DI code: **00840682145640**

Classification rule (93/42/EEC Annex IX) **Rule 10 of Annex IX** Class IIa

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which 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

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/ réf: **DOC2236450** of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by TUV Rheinland Certificate N° HD 60146398 0001
  - harmonized standards applied on the product to which this declaration relates
    - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices



- EN 60601-1:2006/A1:2013 Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:2005/A1:2012)
  - EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)
  - EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)
  - EN 62366:2008 Medical devices — Application of usability engineering to medical devices
  - EN 15223-1:2016 Symbols for Use in the Labeling of Medical Devices
  - EN 1041:2008 Information Supplied by the Manufacturer of Medical Devices
  - EN 62304:2006 Medical device software — Software life-cycle processes (IEC 62304:2006)
  - EN 60601-1-6:2010 Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance- Collateral Standard - Usability
- For the directive 2011/65/EU (RoHS)
    - Technical Documentation/ réf: **DOC2236450** of the product to which this declaration relates
  - For the directive 2014/53/EU (RED)
    - Technical Documentation/ réf: **DOC2236450** of the product to which this declaration relates

14 June 2020

Elizabeth Wentworth  
Regulatory Affairs Leader



**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2096393**  
**LOGIQ E10 – Accessories and Components**

<i>Product Description</i>	<i>Catalogue Designation<sup>1</sup></i>
LOGIQ E10	H4920Z
LOGIQ E10 GEUK mfg.	H4920ZA
LOGIQ E10 CW Console	H4920ZZ
LOGIQ 10 Applications SW	R2.x.x
LOGIQ E10 R1 to R2 Upgrade	H4920Y
<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
C2-7-D-LC Probe	H46422LP
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
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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
LE10 ML6-15 MSK SWE	H4919MS
LOGIQ Exx Scan Assistant	H4919SA
LE10 ML6-15 BRST THY SWE	H4919TB
LOGIQ Exx Contrast SH	H4920CI
LOGIQ Exx Micro B-flow	H4920MB
LOGIQ Exx IC5-9 SWE	H4920PS
LOGIQ Exx Raw Data Capture	H4920RC
LOGIQ Exx Sono A	H4920SA
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 Protective Cover	H4918DC
LOGIQ Exx ECG	H4918EG
LOGIQ Exx EAC Label	H4918EL
LOGIQ Exx Gel Warmer	H4918GW
LOGIQ Exx Power Assistant	H4918PA
LOGIQ Exx Shearwave	H4918SW
LOGIQ Exx Volume Nav	H4918VN
LOGIQ Exx Wireless	H4918WL
KOIOS Breast SW	H4919KO

Accessories <sup>3</sup>	Catalog Designation <sup>1</sup>
BITE HOLE INDICATOR	H45531HS
TEE STORAGE RACK	H45551NM
Ultrasound Probe Rack	E8363JF





VNav Stand (Offboard)	H4908NS
LOGIQ Exx Second Monitor	H4918SM
USB FOOTSWITCH 3 BUTTON	H46732LF
LOGIQ Exx Inkjet Printer	H4918RP
VNAV NT Storage Kit	H4913NS
VNav Probe Sensor	H4913PS
Probe Holder	H4915P
Protective Cover	H4918DC
ADULT TEE SCANHEAD PROTECTION COVER	H45521CK
TEE RS-DLP Adapter	H46352LK
E721 STARTER KIT	E8385MJ
E8C REUSABLE BIOPSY KIT	H40412LN
ML6-15 Biopsy Starter Kit	H40432LJ
C2-7 Biopsy Kit	H40482LK
C2-7 Biopsy Kit Stainless	H40482LL
BE9CS Biopsy Kit 742-339	H42742LH
L2-9 Needle Guide Starter Kit	H44901AM
M5S BIOPSY KIT	H45561FC
C2-6b Needle Guide Pack	H46332LY
RAB BIOPSY STARTER KIT	H46701AE
PEC63 BIOPSY KIT FOR RIC5-9	H46721R
L3-12-D Biopsy Kit	H48302AA
PEC74 BIOPSY KIT FOR RAB LIGHT	H48621Y
C2-9-D Biopsy Starter Kit	H4913BA
C1-6-D Verza Biopsy Starter Kit	H4917VB
Ultra-Pro II needle guide	Z73012FB
C3-10 VNav Holder Starter Kit	H40482LF
IC5-9 V NAV BRACKET	H4908NF
L8-18I V NAV BRACKET	H4908NH
ML6-15 M_BPSY_TRU3D_SKIT	H40432LK
M5Sc-D VNAV bracket	H4908NM
FC389,ECG CABLE SET	H45521AL
ECG CABLE - AHA STYLE	H4910EC
ECG Cables IEC Style	H4911JC
VNav Active Tracker kit	H4913AT
VNav MR Active Tracker	H4915MT
VNav VirtuTRAX Starter Kit	H4910NY
VNav Virtual Tracker	H4911NG
VNav Needle Tracking Kit - 18/20g or less	H4913NT
VNav NEEDLE TRACKING	H4910NT
VNav ETRAX 12 14G ST KT	H4913NU
VNav ETRAX 14 16G ST KT	H4913NV
VNav NT 18/20g	H4913NT



LOGIQ Exx Onboard Printer	H4918BW
SONY UPD25MD COLOR PRINTR	H4911JT
KZ200687 BITE GUARD	H45511EE
KZ693 BITE GUARD OPR.CLIP ON	H45521CB
086A0016 BITE GUARD AD.16*27MM	H45521JH

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.