



EC Declaration of Conformity

Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU, directive 2012/19/EU, directive 2014/53/EU

Manufacturer:

**GE Ultrasound Korea, Ltd.
9, Sunhwan-ro 214beon-gil,
Jungwon-gu, SEONGNAM-SI,
GYEONGGI-DO Republic of Korea**

EU Authorized Representative:

**GE MEDICAL SYSTEMS SCS
283 RUE DE LA MINIERE
78530 BUC
FRANCE**

Equivalent to

**65-1, Sangdaewon-dong,
Jungwon-gu, SEONGNAM-SI
GYEONGGI-DO 462-120 Republic of Korea**

Additional Manufacturing site

**GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES
CRITIKON DE MEXICO S.de R.L. de C.V.,
Calle Valle del Cedro 1551,
Juarez 32575 CHIHUAHUA
MEXICO**

*We hereby declare under our sole responsibility that the class **Ila** product:*

LOGIQ P8, LOGIQ P9, LOGIQ P10 General Purpose Ultrasound Imaging System (ref: See Addendum)

GMDN Code: **40761**

UMDNS Code: **15976**

Classification rule (93/42/EC Annex IX): **Rule 10**

To which this declaration relates, is in conformity with the requirements of:

The medical devices directive 93/42/EEC (MDD)

The directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

The directive 2012/19/EU on the waste electrical and electronic equipment (WEEE)

The directive 2014/53/EU on the radio equipment (RED)

This conformity is based on the following elements:

- Information included in the technical documentation ref.: **DOC1587707** /DHF ref.: **DOC1412680**, of the product to which this declaration relates.



- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42/EEC) delivered by GMED (Notified Body N° 0459) on Certificate Number N° 7697.
- List of harmonized standards applied for CE marking
 - EN 60601-1:2006/A12:2014 (Edition 3.1)
 - EN 60601-1-2:2015
 - EN 60601-1-6:2010/A1:2015
 - EN 60601-2-37: 2008/A1:2015
 - EN 62304:2006/AC: 2008
 - EN 62366:2008 + A1:2015
 - EN 1041:2008
 - EN ISO 15223-1: 2016

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Song, Chae-Rin
Regulatory Affairs Specialist

Date: 28-Apr-2021

GE Healthcare. GE Ultrasound Korea, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu, SEONGNAM-SI,
GYEONGGI-DO REPUBLIC OF KOREA


ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 28-Apr-2021

Product Description	HCAT #	LOGIQ P8	LOGIQ P9	LOGIQ P10	LOGIQ P10 HD
Base Systems					
LOGIQ P8 R4	H43092LH	1	-	-	-
LOGIQ P9 R4	H43092LJ	-	1	-	-
LOGIQ P10 R4	H43092LK	-	-	1	-
LOGIQ P10 R4 HD	H43092LL	-	-	-	1
Probes					
M5Sc-RS Probe	H44901AG	-	-	1	1
C1-6-D Probe	H40472LT	-	1	1	1
C3-10-D Probe	H40482LB	-	-	1	1
C2-7-D Probe	H46422LM	1	1	1	1
10C-D Probe	H46342LA	1	1	1	1
E8C-RS	H40402LN	1	1	1	1
8C-RS	H40402LS	1	1	1	1
12L-RS Probe	H40402LY	1	1	1	1
9L-RS Probe	H40442LL	1	1	1	1
C1-5-RS Probe	H40462LA	1	1	1	1
L8-18i-RS Probe	H40462LF	1	1	1	1
ML6-15-RS Probe	H40462LM	1	1	1	1
BE9CS-RS Probe	H40482LN	1	1	1	1
12S-RS Probe	H44901AB	1	1	1	1
L3-12-RS Probe	H44901AP	1	1	1	1
6S-RS PROBE	H45021RP	1	1	1	1
3Sc-RS Probe	H45041DL	1	1	1	1
6Tc-RS Probe	H45551ZE	1	1	1	1
L3-9i-RS Probe	H46442LK	-	1	1	1
L4-12t-RS Probe	H48062AB	1	1	1	1
L6-12-RS Probe	H48062AC	1	1	1	1
E8Cs-RS Probe	H48062AF	1	1	1	1
P2D Probe	H4830JE	1	1	1	1
P6D Probe	H4830JG	1	1	1	1
Doppler P8D Probe	H46312LZ	1	1	1	1
L10-22-RS	H48312AH	-	1	1	1
RAB2-6-RS Probe	H48681WR	1	1	1	1
IC9-RS Probe	H48691PJ	1	1	1	1
RIC5-9A-RS Probe	H48701EJ	1	1	1	1
Biopsy Options					
3SP Multi-Angle Biopsy	H46222LC	1	1	1	1
M5S Biopsy Kit	H45561FC	-	-	1	1
9L Bio Guide Starter Kit	H4906BK	1	1	1	1



12L-RS Biopsy Starter Kit	H40432LC	1	1	1	1
ML6-15 Biopsy Starter Kit	H40432LJ	1	1	1	1
12L Transverse Bracket	H48392LL	1	1	1	1
Infinite 12L Biopsy Kit	H48392LT	1	1	1	1
L3-12-D Biopsy Kit	H48302AA	1	1	1	1
C1-5 Biopsy Starter Kit	H40432LE	1	1	1	1
C1-6-D Biopsy Starter Kit	H4913BB	-	1	1	1
C2-7 Biopsy Kit	H40482LK	1	1	1	1
C2-7 Biopsy Kit Stainless	H40482LL	1	1	1	1
E721 Starter Kit	E8385MJ	1	1	1	1
E8C E721 E8C-RS IC5-9H MTZ Biopsy Kit	E8333JB	1	1	1	1
E8C Reusable Biopsy Kit	H40412LN	1	1	1	1
BE9CS Biopsy Kit 742-339	H42742LH	1	1	1	1
BE9CS Biopsy Kit 742-401	H42742LJ	1	1	1	1
Reusable Biopsy Needle Guide for GE BE9C Ultrasound Probe	E8387MA	1	1	1	1
Sterile Disposable Biopsy Needle Guide kit for GE BE9C Probe	E8387M	1	1	1	1
IC9-RS Reusable Biopsy Kit	H48701MN	1	1	1	1
IC9 Biopsy Disposable Biopsy Starter Kit	H48691YW	1	1	1	1
RAB6-D Biopsy Starter Kit	H48681ML	1	1	1	1
PEC63 Biopsy Kit for RIC5-9	H46721R	1	1	1	1
RIC5-9A-RS Single Angle Disposable Biopsy Kit	H48681GF	1	1	1	1
TEE PRB Accessory					
ADULT TEE CLIP-ON BITE GUARD	H45511EE	1	1	1	1
ADULT TEE CLIP-ON BITE GUARD OPR.	H45521CB	1	1	1	1
ADULT TEE SCANHEAD PROTECTION COVER	H45521CK	1	1	1	1
ADULT TEE CONVENTIONAL BITE GUARD	H45521JH	1	1	1	1
BITE HOLE INDICATOR	H45531HS	1	1	1	1
TEE PROBES UM EN	H45531RA	1	1	1	1
TEE PROBES UM IT	H45531RD	1	1	1	1
TEE PROBES UM ES	H45531RE	1	1	1	1
TEE PROBES UM PT-PT	H45531RF	1	1	1	1
TEE PROBES UM JA	H45531RG	1	1	1	1



TEE PROBES UM SV	H45531RJ	1	1	1	1
TEE PROBES UM NO	H45531RK	1	1	1	1
TEE PROBES UM DA	H45531RL	1	1	1	1
TEE PROBES UM PL	H45531RM	1	1	1	1
TEE PROBES UM FI	H45531RN	1	1	1	1
TEE PROBES UM EL	H45531RP	1	1	1	1
TEE PROBES UM RU	H45531RQ	1	1	1	1
TEE PROBES UM NL	H45531RR	1	1	1	1
TEE PROBES UM HU	H45531PL	1	1	1	1
TEE PROBES UM SK	H45531PM	1	1	1	1
TEE PROBES UM RO	H45531PN	1	1	1	1
TEE PROBES UM CZ	H45531PP	1	1	1	1
TEE PROBES UM LV	H45531PQ	1	1	1	1
TEE PROBES UM LT	H45531PR	1	1	1	1
TEE PROBES UM TR	H45531PS	1	1	1	1
TEE PROBES UM ET	H45531PT	1	1	1	1
TEE PROBES UM KO	H45531PW	1	1	1	1
TEE PROBES UM SR	H45531ZQ	1	1	1	1
TEE PROBES UM BG	H45531ZR	1	1	1	1
TEE PROBES UM HR	H45531RH	1	1	1	1
TEE PROBES UM ID	H45531CG	1	1	1	1
TEE PROBES UM Port EU	H45531AN	1	1	1	1
TEE PROBES UM Ukrainian	H45531PL	1	1	1	1
TEE PROBES UM SL	H45531PT	1	1	1	1
TEE CLEANING SYSTEM	H45551NK	1	1	1	1
TEE STORAGE RACK	H45551NM	1	1	1	1
Software options					
LP7 and LP9 Advanced 3D	H42782LK	1	1	1	1
LP7 and LP9 Auto IMT	H42782LL	1	1	1	1
LP7 and LP9 DICOM	H42782LR	1	1	1	1
LP7 and LP9 Elastography	H42782LS	1	1	1	1
LP7 and LP9 Elastography Quantification	H42782LT	1	1	1	1
LP7 and LP9 Flow Quantification	H42782LW	1	1	1	1
LP7 and LP9 LOGIQView	H42782LY	1	1	1	1
LP7 and LP9 Report Writer	H42782LZ	1	1	1	1
LP7 and LP9 Scan Assistant	H42792LA	1	1	1	1
LP7 and LP9 Stress Echo	H42792LB	1	1	1	1
LP7 and LP9 Tissue Velocity Imaging TVI	H42792LC	1	1	1	1



LP7 and LP9 B Steer+	H42792LD	1	1	1	1
LP7 and LP9 4D TUI Software	H42792LF	1	1	1	1
LP7 and LP9 VOCAL Software	H42792LG	1	1	1	1
LP7 and LP9 VCI Static Software	H42792LH	1	1	1	1
LP7 and LP9 Auto EF	H42792LJ	1	1	1	1
LP7 and LP9 Meas Assist Breast	H42792LK	1	1	1	1
LP7 and LP9 Meas Assist OB	H42792LL	1	1	1	1
LP7 and LP9 Breast Prod	H42792LM	1	1	1	1
LP7 and LP9 Compare Assistant	H42792LN	1	1	1	1
LP7 and LP9 Thyroid Prod	H42792LP	1	1	1	1
LP7 and LP9 SWDVR	H42792LR	1	1	1	1
SWDVR Basic	H42922LY	1	1	1	1
LP7-P9 R2 Cardiac Strain	H42822LY	1	1	1	1
LP7-P9 STIC	H42822LZ	1	1	1	1
LP7-P9 Omniview	H42832LA	1	1	1	1
LP7-P9 R3 HD B-Flow	H42892LR	1	1	1	1
LP7-P9 R3 CEUS	H42892LS	1	1	1	1
LP7-P9 R3 HRes CEUS	H42892LT	1	1	1	1
LP7-P9 R3 HDLive	H42892LW	1	1	1	1
LP7-P9 R3 ShearWave	H42892LY	1	1	1	1
LOGIQ P Apps without Dongle	H42922LM	1	1	1	1
KOIOS SW for LOGIQ P8 P9 P10 R4	H43122LW	1	1	1	1
LOGIQ E10 KOIOS Install	H4919KI	1	1	1	1
UGAP	H43122LK	1	1	1	1
SonoNT SonoIT	H43122LL	1	1	1	1
Sono AVC for Renal	H43122LR	1	1	1	1
Hepatic Assistant	H43132LR	1	1	1	1
Hardware options					
Pencil Probe CW HW Kit for LOGIQ P8 P9 P10 R4	H43132LM	1	1	1	1
LP7 and LP9 4D Kit	H42802LD	1	1	1	1
LP7-P9 R2 Battery option	H42832LG	1	1	1	1
LP7-P9 UVC S300	H42832LJ	1	1	1	1
LP7-P9 UVC S300 Japan	H42832LK	1	1	1	1
LOGIQ P Apps	H42892LZ	1	1	1	1
LP7-P9 R3 ext battery	H42902LM	1	1	1	1



LP7-P9 R3 R3 ODD Option	H42912LE	1	1	1	1
Pwr supply noise filter	H46162LH	1	1	1	1
LP7 P9 CW HW Kit	H46432LN	1	1	1	1
USB FOOTSWITCH 3 BUTTON	H46732LF	1	1	1	1
ISOLATION TRANSFORMER	H48671WN	1	1	1	1
USB barcode reader	H43132LZ	1	1	1	1
Ethernet Protection Cable	H43272LJ	1	1	1	1
ECG options					
ECG Module Option Kit for LOGIQ P8 P9 P10 R4	H43122LZ	1	1	1	1
ECG CABLE - AHA STYLE	H4910EC	1	1	1	1
ECG CABLES IEC STYLE	H4911JC	1	1	1	1
ME Option					
LP7 AND LP9 PAPER TRAY	H42802LE	1	1	1	1
LP7 AND LP9 OPIO TRAY	H42802LG	1	1	1	1
LP7-P9 R3 Rear handle	H42902LC	1	1	1	1
LP7-P9 R3 Cable Hook rear	H42902LD	1	1	1	1
LP7-P9 R3 Gel Warmer	H42902LE	1	1	1	1
LP7-P9 R3 High Cabinet	H42902LG	1	1	1	1
LP7-P9 R3 Drawer	H42902LH	1	1	1	1
LP7-P9 R3 Low Cabinet	H42902LJ	1	1	1	1
LP7-P9 R3 Multi P. holder	H42902LK	1	1	1	1
PROBE CABLE HANGER	H44412LA	1	1	1	1
LOGIQ S7 R3 Small Probe Holder	H46302LB	1	1	1	1
Peripherals					
Printers					
UP-D25MD PRINTER	H44642LW	1	1	1	1
BW Printer Installation Kit for LOGIQ P8 P9 P10 R4	H43132LN	1	1	1	1
UP-D898 BW Printer Kit	H46992LS	1	1	1	1
Wireless LAN					
LP7 P9 W. LESS LAN KIT	H42802LL	1	1	1	1
Power Cords					
Power Cord 220V EU	H46342LZ	1	1	1	1
PWR CORD DK HSP C13 RED	H46712LT	1	1	1	1
PWR CORD DK STD C13 GRY	H46692LK	1	1	1	1



Destination Sets					
LP7-P9 Destination set JAPAN	H40392LA	1	1	1	1
DESTINATION SET TAIWAN	H44512LY	1	1	1	1
DESTINATION SET UK	H46712LM	1	1	1	1
DESTINATION SET S AFRICA	H46712LN	1	1	1	1
DESTINATION SET ARGENTINA	H46712LP	1	1	1	1
DESTINATION SET ISRAEL	H46712LR	1	1	1	1
DESTINATION SET SWISS	H46712LS	1	1	1	1
DESTINATION SET US	H46712LW	1	1	1	1
DESTINATION KIT AUS_NZ	H46712LZ	1	1	1	1
DESTINATION SET CHINA	H46722LA	1	1	1	1
DESTINATION SET INDIA	H46722LB	1	1	1	1
DESTINATION SET ITALY	H46722LD	1	1	1	1
DESTINATION SET BRAZIL	H46752LW	1	1	1	1
Keyboards and Key Cap Language Kits					
AN Keyb. Greek black	H42902LR	1	1	1	1
AN Keyb. Norwegian black	H42902LS	1	1	1	1
AN Keyb. Russian black	H42902LT	1	1	1	1
AN Keyb. French black	H42902LW	1	1	1	1
AN Keyb. Swedish black	H42902LY	1	1	1	1
AN Keyb. German black	H42902LZ	1	1	1	1
AN Keyb. English black	H42912LA	1	1	1	1
Upgrade kit					
LP9 R3 to R4 SW conversion	H43092LM	-	1	-	-
Veterinary Use Only					
Vet kit	H46832LC	1	1	1	1
Vet probe caution label	H48492AW	1	1	1	1

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 Ultrasound Korea Ltd. has verified the mutual compatibility of the devices in combination with LOGIQ P10, LOGIQ P9, LOGIQ P8 and included relevant information to users with the LOGIQ P10, LOGIQ P9 and LOGIQ P8 instructions for use.

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