



## **EC DECLARATION OF CONFORMITY**

(Following the provisions of the medical devices directive 93/42/EEC)

We

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 Minière  
78533 BUC, France**

Equivalent to

**65-1, Sangdaewon-dong,  
Jungwon-gu, Seongnam-si  
Gyeonggi-do 462-120, Korea**

Declare under our sole responsibility that the class IIa device:

**LOGIQ S8 including accessories and components  
Ref. See addendum  
GMDN Code: 40761  
UMDNS Code: 15-976  
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 which apply to it.

This conformity is based on the following elements:

- Information included in the documents:  
Design History File Ref./ réf. : **DOC0940871**, 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 27 August 2013 / Certificate N °7697
- (If applicable) List of harmonized standards applied for CE marking
  - *EN 60601-1: 2006 / AC2010*
  - *EN 60601-1-2 : 2007 / AC2010*
  - *EN 60601-1-6 : 2010*
  - *EN 60601-2-37 : 2008*
  - *EN 62304 : 2006*
  - *EN ISO 13485 : 2012 / AC2012*
  - *EN ISO 14971 : 2012*



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- EN 62366 : 2006
  - ISO EN 980 : 2008
  - ISO EN 1041 : 2008

A handwritten signature in black ink, appearing to be 'Kim, Chansook'.

Oct. 18. 2013

Date: Oct-18-2013

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Kim, Chansook (Emilliana)  
Regulatory Affairs Leader

GE Healthcare. GE Ultrasound Korea, Ltd.  
65-1, Sangdaewon-dong, Jungwon-gu, Seongnam-si,  
Gyeonggi-do, 462-120, Korea

**ADDENDUM TO THE EC DECLARATION OF CONFORMITY****Dated 18-October-2013**

Product Description	Catalog Number
<b>Ultrasound console</b>	R1, R2
LOGIQ S8	R1 (H45332LG, H45332LH, H45332LJ, H45332LK H45332LL, H45332LM, H45332LN) R2(H46342LT, H46342LW)
<b>Transducers</b>	
C1-5-D Convex Transducer	H40452LE
3CRF-D Microconvex Transducer (D connector)	H40462LK
IC5-9-D Microconvex Intracavitary Transducer	H40442LK
9L-D Linear Transducer	H40442LM
ML6-15-D Matrix Linear Transducer	H40452LG
L8-18i-D Linear Transducer	H40452LL
M5S Sector Transducer	H45551NH
S4-10 Sector Transducer	H45302LA
P2D 2 MHz CW Pencil Probe	H4830JE
P6D 6MHz CW Pencil Probe	H4830JG
3SP-D PHASED ARRAY PROBE	H48681AZ
11L-D PROBE	H40432LN
RAB6-D Probe	H48681MG
RIC 5-9D 4D Intracavitary Transducer	H48651MS
S1-5-D Probe	H4913SD
6Tc-RS Probe	H45551ZE
C2-6b-D probe	H46332LW
10C-D probe	H46342LA
6S-D Probe	H45021RR
<b>ECG module</b>	
ECG Module (without ECG cables)	H45302LB
ECG cables AHA	H45302LY
ECG Cables IEC	H45302LZ
<b>Biopsy Bracket</b>	
9L-D Multi angle Biopsy Starter Kit	H4906BK
C1-5-D Multi angle Biopsy Starter Kit	H40432LE
ML6-15-D Multi angle Biopsy Starter Kit	H40432LJ
IC5-9-D Disposable Biopsy kit	E8385MJ
IC5-9-D Reusable Biopsy Kit	H40412LN
3CRF Biopsy Starter Kit - 13.1cm	H40442LR
3CRF Multiline Biopsy Starter Kit - 2.7 and 13.1cm	H40452LP
12L-RS MULTI BIOPSY GUIDE	H40432LC
S1-5 Multi Angle Biopsy Starter Kit	H4908SD



RAB-6 Multi Angle Biopsy Kit	H48681ML
RIC5-9-D Reusable Biopsy Kit	H46721R
C2-6b Integrated Needle Guide	H46332LY
<b>Software options</b>	
Advanced 3D	H45342LA
Auto IMT	H45342LB
B-Flow	H45342LC
Coded Contrast Imaging	H45342LD
CW Doppler	H45342LE
DICOM	H45342LF
Elastography	H45342LG
Elasto QA	H45342LH
Flow QA	H45342LJ
LOGIQView	H45342LK
Report Writer	H45342LL
Scan Assistant	H45342LM
Stress Echo	H45342LN
TVI (Tissue Velocity Imaging)	H45342LP
Auto EF	H46342LF
Breast Productivity Package	H46342LK
B-Steer+	H46342LR
Compare Assistant	H46342LL
Measure Assistant - Breast	H46342LH
Measure Assistant - OB	H46342LJ
Thyroid Productivity Package	H46342LM
TUI (Thomographic Ultrasound)	H46342LB
VCI Static	H46342LD
VOCAL_II	H46342LC
<b>Hardware options</b>	
Pencil Probe CW HW Kit	H45302LJ
Probe holder adapter for small probes	H45302LS
Side Tray	H45302LH
LS8 DVR Kit	H45302LT
USB 3 Pedal Foot Switch	H46732LF
LS8 Endocavity probe holder	H45302LK
LS8 Side Probe Holder	H45302LL
LS8 Realtime 4D	H46342LE
Power Assistant Hardware	H46352LB
Battery Pack for Power Assistant	H46352LC
TEE RS-DLP Adapter	H46352LK
Wireless LAN	H46352LD