



## EC Declaration of Conformity

### EG Konformitätserklärung

Document No. DOC 0787264

*Manufacturer/ Hersteller:*  
GE Ultrasound Korea Ltd  
65-1, Sangdaewon-dong  
Jungwon-gu, Seongnam-si  
Gyeonggi-do 462-120, Korea

*Authorized EU Representative/ EU Repräsentant:*  
**GE Medical Systems Information  
Technologies GmbH**  
Munzingerstrasse 5  
79111 Freiburg, Germany

We herewith declare that the product/ *Wir erklären hiermit, dass das Produkt*

### **LOGIQ P5 Diagnostic Ultrasound Imaging System, Version 4**

(including system components and accessories/einschließlich Systemkomponenten und Zubehör)

UMDNS-Code: 15-976; GMDN-Code: 40761

fulfills the requirements of the following directives, standards and normative documents:  
*mit den folgenden Richtlinien, Normen und normativen Dokumenten übereinstimmt:*

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
2. EN 60601-1:1990 Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988) with : Amendment A1:1993 to EN 60601-1:1990 (IEC 60601-1:1988/A1:1991) and Amendment A2:1995 to EN 60601-1:1990 (IEC 60601-1:1988/A2:1995), EN 60601-1:2006 Medical Electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
3. EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000)
4. EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001) with Amendment A1:2006 to EN 60601-1-2:2001 (IEC 60601-1-2:2001/A1:2004) AND EN 55011:1991 / CISPR 11:1990 modified, device group 1, class A, EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007)
5. EN 60601-2-37:2001 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001) with Amendment A1:2005 to EN 60601-2-37:2001 (IEC 60601-2-37:2001/A1:2004) and Amendment A2:2005 to EN 60601-2-37:2001 (IEC 60601-2-37:2001/A2:2005), EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)
6. EN 60601-1-4:1996/A1:1999 Medical electrical eEquipment - Part 1-4- General requirements for safety- Collateral standard: Programable electrical medical systems (IEC 60601-1-4:1996/A1:1999)
7. EN 60601-1-6:2007 Medical electrical equipment – Part 1-6- General requirements for basic safety and essential performance- Collateral standard: Usability (IEC 60601-1-6:2006)

Compliance of the designated product with the Directive 93/42/EEC has been certified by:  
*Die Übereinstimmung des bezeichneten Produktes mit der Richtlinie 93/42/EWG wird bescheinigt durch:*

**GE Ultrasound Korea Ltd.**  
**Technical Dossier DOC0787261**

The medical device has been assigned to class **IIa** as specified in the Directive 93/42/EEC. It bears the mark

*Das Medizinprodukt ist eingestuft in die Klasse **IIa** gemäss der Richtlinie 93/42/EWG, es trägt die Kennzeichnung*



The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

*Das bezeichnete Produkt wurde unter Anwendung des Qualitätsmanagementsystems gemäss ISO 13485:2003 und Anhang II der Richtlinie 93/42/EWG über Medizinprodukte entwickelt, hergestellt und geprüft. Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:*

 LNE/G-MED France

Seongnam /Korea , Oct. 4<sup>th</sup>. 2010

*Kim, Hyeonho Kim – RA Leader*

The technical documentation is filed at/ Die technische Dokumentation ist archiviert bei  
GE Ultrasound Korea



# GE Healthcare

	Remark	Identification No. (Catalog No.)
System	LP5 PRO BT11 FOR EUROPE	H44662LP
	LP5 PREMIUM BT11 EUROPE	H44662LY
	LP5 PREMIUM BT11 EUROPE	H44672LM
	LP5 BT11 OB for Europe	H44672LH
	LP5 PREMIUM BT11 EUROPE / KOREA	H44672LM
Add-on (Option)	ENDO PROBE HOLDER	H44442LR
	BW PRINTER FIXTURE KBD	H44442LT
	BW PRINTER FIXTURE MIDDLE	H44442LW
	PRINTER VCR DVD FIXTURE	H44442LY
	COLOR PRINTER FIXTURE MID	H44442LZ
	REAR HANDLE	H44452LA
	LCD FLEXIBLE ARM KIT	H44552LN
	DRAWER	H44412LC
	PROTECT COVER	H44412LZ
	ADDITIONAL TASK LAMP KIT	H44412LD
	MICROPHONE	H44452LE
	PAPER HOLDER	H44452LB
	PROBE CABLE HANGER	H44412LA
	3 BUTTONS FOOT SWITCH	H44552LS
	1 BUTTON FOOT SWITCH	H44552LR
	QWERT KEY_GREEK	H44452LC
	QWERT KEY_RUSSIAN	H44452LD
	QWERT KEY_SWEDISH	H44412LW
	QWERT KEY_NORWEGIAN	H44412LY
	CW DOPPLER KIT	H44402LP
	4D UPGRADEKIT_PROBEHOLDER	H44482LS
	SWIVELLOCK CASTER	H44472LY
	3 PROBE PORTS KIT	H44402LS
	LP5 LA5 UPS BRKT KIT	H44482LZ
	HIGH QUALITY VIDEO SIGNAL	H44522LB
	BT08 NETWORK UPKIT	H44522LC
	GASTOR PROBE UPKIT	H44522LD
	STERILE KEYBOARD COVER	H44492LL
	LA5 REAR SWIVEL CASTER	H44552LP
	BT08 UPKIT WITH LG DVD	H44492LP
	ARC SWITCH SET	H44592LA
	BT11 Upkit	H44682LA
	BT11 CPU Upkit	H44682LF
	ECG KIT LHI IEC CABLE LP5	H44642LM
	ECG KIT LHI AHA CABLE LP5	H44642LN
	P5 BT09 UPKIT WITH CWD	H44602LP
BT09 CWD KIT FOR P5/P6PRO	H46102LK	
BT11 BW Printer Fixture Middle	H44682LG	
BT11 Drawer	H44682LH	

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BT11 MTZ Probe holder	H44682LJ
DVO 1000 MD Fixture Top	H44682LK
D25MD PRINTER Fixture Middle	H44642LS
D25MD PRINTER Fixture Top	H44642LT
P5/A5 EASY 3D SW	H44602LA
P5/A5 ADVANCED 3D SW	H44602LB
P5/A5 DICOM SW	H44602LC
P5/A5 LOGIQ VIEW SW	H44602LD
P5/A5 ANATOMICAL M MODE	H44602LE
P5/A5 B-FLOW SW	H44602LF
P5/A5 REPORT DESIGNER SW	H44602LG
P5/A5 CROSSBEAM SW	H44602LH
P5/A5 CHA SW	H44602LJ
P5/A5 SRI HD SW	H44602LK
P5/A5 PDF WRITER SW	H44602LL
DB VIEWER	H44492LW
TVI TVD	H44682LB
Stress Echo	H44682LC
Elastography on 11L	H44682LD
Auto IMT	H44682LE
LP5 BUM ENGLISH	H44692LA
LP5 BUM FRENCH	H44692LB
LP5 BUM GERMAN	H44692LC
LP5 BUM SPANISH	H44692LD
LP5 BUM PORTUGUESE	H44692LE
LP5 BUM ITALIAN	H44692LF
LP5 ARM	H44692LT
LP5 SERVICEMANUAL	H44692LW
LP5 EDOCS CD	H44692LY
LP5 USER GUIDE SWEDISH	H44692LZ
LP5 USER GUIDE POLISH	H44702LB
LP5 USER GUIDE GREEK	H44702LC
LP5 USER GUIDE DANISH	H44702LD
LP5 USER GUIDE NORWEGIAN	H44702LE
LP5 USER GUIDE FINNISH	H44702LF
LP5 USER GUIDE DUTCH	H44702LG
LP5 USER GUIDE ICELANDIC	H44702LH
LP5 USER GUIDE ESTONIAN	H44702LJ
LP5 UG TRADITIONALCHINESE	H44702LK
LP5 USER GUIDE HUNGARIAN	H44702LM
LP5 USER GUIDE SLOVAKIAN	H44702LN
LP5 USER GUIDE CRECH	H44702LP
LP5 USER GUIDE ROMANIAN	H44702LS
LP5 USER GUIDE LITHUANIAN	H44702LT
LP5 USER GUIDE LATVIAN	H44702LW
LP5 USER GUIDE SERBIAN	H44702LY



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LP5 USER GUIDE BULGARIAN	H44702LZ
LP5 UG EUROPEANPORTUGUESE	H44712LB
LP5 HARD COPY KIT ENGLISH	H44712LC
LP5 HARD COPY KIT FRENCH	H44712LD
LP5 HARD COPY KIT GERMAN	H44712LE
LP5 HARD COPY KIT SPANISH	H44712LF
LP5 HC KIT PORTUGUESE	H44712LG
LP5 HARD COPY KIT ITALIAN	H44712LH
LP5 DOC KIT ENGLISH	H44712LL
LP5 DOC KIT FRENCH	H44712LM
LP5 DOC KIT GERMAN	H44712LN
LP5 DOC KIT SPANISH	H44712LP
LP5 DOC KIT PORTUGUESE	H44712LR
LP5 DOC KIT ITALIAN	H44712LS
3.5C/3.5CS Single Biopsy	E8385MG
4C/5CS Multi-angle	E8385NA
E8C/E8CS reusable single-angle	H40412LN
E8C/E8CS disposal single-angle	E8385MJ
E8C/E8CS disposale	E8333JA
E8C/E8CS disposale -guide and covers	E8333JB
BE9C/BE9CS reusable	E8387MA
8L multi-angle	E8385N
BE9C/BE9CS Disposal	E8387M
9L multi-angle	H4906BK
10L multi-angle	E8386RJ
11L multi-angle	H40432LC
12L single-angle	E8385MM
t739 multi-angle	E8386RG
3CRF single-angle	H40442LR
3CRF multi-angle	H40452LP
3S-02 multi-angle	E8385MZ
5S-02 multi-angle	E8385MZ
4D3C-L, 4D5C-L single angle (Kretz)	H48621Y
4D3C-L, 4D5C-L single angle (Civco)	H46701AE
4DE7C single-angle	H46721R
4D8C single angle (Civco)	H46701AF
4D8C single angle (Kretz)	H48651DG
ERB bridge (fixed) type biopsy guide	H40202E
ERB Stepper (grid) type biopsy guide	H40342LL
3Sp Multi-angle biopsy	H46222LC
5Sp Multi-angle biopsy	H46222LD
POWER CORD FOR UK/HK	H44482LB
POWER CORD FOR ITALY	H44482LC
POWER CORD FOR DENMARK	H44482LD
POWERCORD FOR SWITZERLAND	H44482LF
4C	H4904PC

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5CS	H4001DC
8C	H40412LJ
E8CS	H44801HR
9L	H40412LT
10L	H40412LG
11L	H40412LY
i739	H40212LF
T739	H40212LM
3S-02	H4701SZ
5S-02	H40422LA
7S-02	H40422LB
4D3C-L	H44801G
4DE7C	H44801GA
ERB	H45202ER
BE9CS	H40452LF
UG7C	H40432LA
P2D	H4830JE
P6D	H4830JG
3.5CS	H40412LK
3.5C	H4901PE
E8C	H40412LE
8L	H4001DB
12L	H40412LH
BE9C	H40412LW
3CRF	H40442LP
3Sp PROBE	H46222LE
5Sp PROBE	H46222LF
4D8C	H44801GZ
I12L PROBE	H4012L