



DECLARATION CE DE CONFORMITE

(suivant les dispositions de la directive relative aux dispositifs médicaux 93/42/CEE)

EC DECLARATION OF CONFORMITY

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

Nous / We

Fabricant / Manufacturer:

GE Ultrasound Korea
65-1, Sangdaewon-Dong, Chungwon-Ku
Sungnam-Si, Kyunnggi-Do, Korea 462-120

Responsable U.E / E.U-Responsible

GE Medical Systems S.C.S
283 rue de la Minière
78530 BUC France

déclarons, sous notre seule responsabilité, que le produit de classe II a :
declare under our sole responsibility that the class IIa product:

LOGIQ 5 Expert

Ultrasound System, Imaging, General Purpose

Réf. / Ref.: H40242LB

GMDN Code: **40761**

auquel cette déclaration se rapporte, est en conformité avec les exigences essentielles qui lui sont applicables (annexe I de la directive relative aux dispositifs médicaux 93/42/CEE).

to which this declaration relates is in conformity with the essential requirements which apply to it (annex I of the medical devices directive 93/42/EEC).

Cette conformité s'appuie sur les éléments suivants / *This conformity is based on the following elements:*

- Informations contenues dans le(s) document(s) / *Information included in the document(s):*
Dossier historique de conception / *Design History File* Réf./ ref.: **SED-UJT-H12** rév. / rev.: 6
du produit auquel cette déclaration se rapporte / *of the product to which this declaration relates.*
- Attestation CE d'approbation du système complet d'assurance qualité (annexe II de la directive relative aux dispositifs médicaux 93/42/CEE) délivrée par le G-MED (Organisme Notifié n°0459) / *EC certificate: approval of full quality assurance system (annex II of the medical devices directive 93/42 EEC) delivered by G-MED (Notified Body n°0459)*
Attestation / *Certificate* N° 0984/B2P3/1

Seoul, 9 mai 2006
May 9th, 2006

Nak-Chool Kim
QASR Manager
Representative of QA System
GE Ultrasound Korea

Cette déclaration CE de conformité remplace la précédente déclaration datée du 28 octobre 2005.
This EC declaration of conformity supersedes the previous declaration dated Oct. 28th, 2005.



ADDENDUM A LA DECLARATION CE de CONFORMITE datée du 9 mai 2006
Addendum à la Déclaration CE de Conformité dated May 9th, 2006

	Nom / Name	Identification No. (Catalog No.)
Système / System	LOGIQ 5 Expert	H40242LB
Add-on (Option) <i>Add-on (Option)</i>	Foot Switch	H41332LR
	Fixture for VCR/Color printer, side pocket	H41312LK
	Fixture for VCR/Color printer, Top	H41312LL
	Cable set for Sony VCR	H41312LP
	ECG Install Kit	H41312LF
	Basic Users Manual (English)	H41302LP
	Basic Service Manual (English)	H41302LT
	Quick Start Guide (English)	H41302LS
	Easy 3D Software	H41312LB
	Advanced 3D Software	H41312LC
	CW Doppler kit with ATD Assy.	H41312LG
	CW Doppler kit without ATD Assy.	H41332LH
	DICOM Software	H41312LD
	Additional probe port install kit	H41312LA
	BW Printer Fixture kit	H41312LJ
	BW Printer Cable set	H41312LM
	Insite Modem Kit	H41332LG
	Color Printer Cable set	H41312LN
	1.3 GB MOD Install kit	H41312LE
	Insite software	H41312LT
	Russian language kit	H41312LR
	Greek language kit	H41312LS
	LOGIQ View option kit	H41332LJ
	Cable set for digital BW printer	H41332LE
	Cable set for digital Color printer	H41332LF
	Cable set for Panasonic VCR	H41332LH
	Swivel Lock option	H41312LW
	Anatomical m Mode Option	H41332LB
	Advanced reference manual	H41312LZ
	BT03 upgrade kit	H41332LS
	B-Flow option	H41332LT
	CHA option	H41332LW
	ECG Cable (Clip)	H44012LK
	L5 Basic Up kit for BEP1	H41362LD
	L5 Basic Up kit for BEP2	H41362LE
	L5 Basic Horizon kit for BEP1	H41362LB
	L5 Basic Horizon kit for BEP2	H41362LC
	L5 Basic Horizon kit for Basic	H41362LF
	LOGIQ 5 EXPERT Hard Copy KIT English	H41292LJ
	LOGIQ 5 EXPERT Hard Copy KIT French	H41292LK
	LOGIQ 5 EXPERT Hard Copy KIT Spanish	H41292LL
LOGIQ 5 EXPERT Hard Copy KIT Italian	H41292LM	
LOGIQ 5 EXPERT Hard Copy KIT German	H41292LN	
LOGIQ 5 EXPERT Hard Copy KIT Portuguese	H41292LP	
LOGIQ 5 EXPERT Hard Copy KIT Chinese	H41292LR	
LOGIQ 5 EXPERT Hard Copy KIT Japanese	H40342LG	
LOGIQ 5 EXPERT Documentation KIT English	H41382LW	
LOGIQ 5 EXPERT Documentation KIT French	H41382LY	
LOGIQ 5 EXPERT Documentation KIT Spanish	H41382LZ	
LOGIQ 5 EXPERT Documentation KIT Italian	H41392LA	
LOGIQ 5 EXPERT Documentation KIT German	H41392LB	



	Nom / Name	Identification No. (Catalog No.)
Add-on (Option) <i>Add-on (Option)</i>	<i>LOGIQ 5 EXPERT Documentation KIT Portuguese</i>	H41392LC
	<i>LOGIQ 5 EXPERT Documentation KIT Chinese</i>	H41392LD
	<i>LOGIQ 5 EXPERT Documentation KIT Japanese</i>	H40342LH
	<i>LOGIQ 5 Expert eDOCS CD</i>	H41322LL
	<i>Medical Ultrasound Safety Pamphlet</i>	H43032LT
	<i>LOGIQ 5 Expert Advanced Reference Manual</i>	H41302LR
	<i>LOGIQ 5 EXPERT Basic User Manual French</i>	H41362LT
	<i>LOGIQ 5 EXPERT Basic User Manual Spanish</i>	H41362LW
	<i>LOGIQ 5 EXPERT Basic User Manual Italian</i>	H41362LY
	<i>LOGIQ 5 EXPERT Basic User Manual German</i>	H41362LZ
	<i>LOGIQ 5 EXPERT Basic User Manual Portuguese</i>	H41372LA
	<i>LOGIQ 5 EXPERT Basic User Manual Chinese</i>	H41372LK
	<i>LOGIQ 5 EXPERT Quick Start Guide French</i>	H41352LS
	<i>LOGIQ 5 EXPERT Quick Start Guide Spanish</i>	H41352LT
	<i>LOGIQ 5 EXPERT Quick Start Guide Italian</i>	H41352LW
	<i>LOGIQ 5 EXPERT Quick Start Guide German</i>	H41352LY
	<i>LOGIQ 5 EXPERT Quick Start Guide Portuguese</i>	H41352LZ
	<i>LOGIQ 5 EXPERT Quick Start Guide Chinese</i>	H41372LM
	<i>Manual BE9C English</i>	H40422LC
	<i>Manual BE9C French</i>	H40422LD
	<i>Manual BE9C German</i>	H40422LE
	<i>Manual BE9C Spanish</i>	H40422LF
	<i>Manual BE9C Portuguese</i>	H40422LG
	<i>Manual BE9C Italian</i>	H40422LH
	<i>Manual BE9C Chinese</i>	H40302LH
	<i>Manual E8C English</i>	H44801GK
	<i>Manual E8C French</i>	H44801GL
	<i>Manual E8C German</i>	H44801GN
	<i>Manual E8C Spanish</i>	H44801GM
	<i>Manual E8C Portuguese</i>	H44801GR
	<i>Manual E8C Italian</i>	H44801GP
	<i>Manual E8C Chinese</i>	H40302LR
<i>BT05 Up kit for LOGIQ5 Expert</i>	H40382LS	
<i>UG7C probe installation kit for Europe (LOGIQ5-Expert/Pro)</i>	H41392LZ	
Add-on (Sonde) <i>Add-on (Probe)</i>	5C	H40402LB
	3C	H40412LB
	3.5C	H4901PE
	3S	H4550SZ
	10L	H40412LG
	12L	H40412LH
	E8C	H40412LE
	6D	H4830JG
	8C	H79202NL
	7L	H40412LF
	10S	H4901PC
	2D	H4830JE
	BE9C	H79272NL
	i12L	H4012L
	3.5CS	H40412LK
	7S	H40422LB
	I739	H40212LF
	T739	H40212LM
	ERB	H45202ER
	5S	H40422LA
	UG7C	H40432LA



	Nom / Name	Identification No. (Catalog No.)
Accessoires / <i>Accessories</i>	<i>3C Biopsy Starter Kit (Multi angle)</i>	<i>H40412LB</i>
	<i>3.5C Single-angle Biopsy Starter Kit</i>	<i>H4901PE</i>
	<i>5C Biopsy Starter Kit (Multi angle)</i>	<i>H40412LA</i>
	<i>E721/E8C Biopsy Starter Kit</i>	<i>H40412LE</i>
	<i>10L Biopsy Starter Kit (Multi angle)</i>	<i>H40412LG</i>
	<i>12L Biopsy Starter Kit (Fixed angle)</i>	<i>H40412LH</i>
	<i>7L Biopsy Starter Kit (Multi angle)</i>	<i>E8385PC</i>
	<i>3S Biopsy Starter Kit (Multi angle)</i>	<i>E8385MZ</i>
	<i>T739 Biopsy Starter Kit (Multi angle)</i>	<i>E8386RG</i>
	<i>ERB Biopsy Starter Kit (fixed angle)</i>	<i>H78112P</i>
	<i>ERB Biopsy Starter Kit (grid)</i>	<i>H40342LL</i>
Manuels d'installation / <i>Instruction Manual for Installation</i>	Probes	Caution Sheet
	Insite modem installation instruction	2331698 Rev.0
	BW Printer Installation Instruction	2331700 Rev.0
	ECG Installation Instruction	2331699 Rev.2
	VCR Installation Instruction	2331701 Rev.0
	Additional probe port installation instruction	2331903 Rev.0
	MOD Option Installation Instruction	2331703 Rev.0
	Foot switch Installation Instruction	2331702 Rev.0
	Software Option Installation Instruction	2331704 Rev.1
	Swivel Lock Installation Instruction	2335269 Rev.0
	CW Doppler kit Installation Instruction	2374461 Rev.1
	L5 BTO3 Basic upgrade kit installation instruction	2401896 Rev.1
	L5 BTO3 Horizon upgrade kit installation instruction	2401516 Rev.1
	L5 BTO3 Horizon for basic upgrade kit installation instruction	2401897 Rev.1
	BTO5 Up kit for LOGIQ5-Expert installation instruction	5133499 Rev.1
BTO5 Up kit for LOGIQ5-Pro/Expert installation instruction	5135618 Rev.1	