ATTESTATION / *CERTIFICATE* **N° 7697 rev. 19**

Délivrée à Paris le 17 mars 2021

Issued in Paris on March 17th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE ULTRASOUND KOREA, Ltd.

9, Sunhwan-ro 214beon-gil, Jungwon-gu,

SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositif ou système de diagnostic par ultrasons

Ultrasound diagnostic device or system

Voir document complémentaire GMED / See GMED additional document

n° 36988

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P183396, P601203, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P183396, P601203, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **March 17th, 2021 (included)**

Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED GROUPE LNE

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Lionel DREUX
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Lionel DREUX
Certification Director

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GMED - 7697 rev. 19
Modifie le certificat 7697-18

Ce document complémentaire GMED n° 36988 rev. 1 atteste de la validité du certificat CE N° 7697 rev. 19 au regard des informations listées ci-dessous.

This GMED additional document n° 36988 rev. 1 attests to the validity of EC certificate N° 7697 rev. 19 with regard to the information listed below.

Fabricant / *Manufacturer:* **GE ULTRASOUND KOREA, Ltd.**
9, Sunhwan-ro 214beon-gil, Jungwon-gu,
SEONGNAM-SI, GYEONGGI-DO, REPUBLIC OF KOREA

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P7**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P9**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ P10**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S6**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S8t**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10**	**IIa**

GMED 0459

GMED - 36988 rev. 1
Modifie le document n° 36988 rev.0

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Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON S10 Expert**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P6**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON P8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON SWIFT**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**VOLUSON SWIFT+**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S8**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S8 T1**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Expert**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 Pro**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ S7 XDclear2.0**	**IIa**
Dispositif ou système de diagnostic par ultrasons *Ultrasound diagnostic device or system*	**LOGIQ E10s**	**IIa**

Site couvert et Activités / *Location and Activities*

Site / *Location*	**Activités** / *Activities*
GE ULTRASOUND KOREA, Ltd. **9, Sunhwan-ro 214beon-gil, Jungwon-gu,** **Seongnam-si, Gyeonggi-do, REPUBLIC OF KOREA** **équivalent à** *equivalent to* **GE ULTRASOUND KOREA, Ltd.** **65-1, Sangdaewon-dong, Jungwon-gu,** **Seongnam-si, Gyeonggi-do - 462-120 REPUBLIC OF KOREA**	**Conception, fabrication et contrôle final** *Design, manufacture and final control*

GMED 0459

GMED - 36988 rev. 1
Modifie le document n° 36988 rev.0

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Lionel DREUX
Certification Director

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

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

LOGIQ P7, LOGIQ P9, General Purpose Ultrasound Imaging System including accessories and components (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)
The Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

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**

This EC declaration of conformity supersedes the previous declaration dated **26-Mar-2019.**

Soyoung Park

Date/*Datum*: 17-May-2019

Park, Soyoung
Regulatory Affairs Specialist

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 17-May-2019

- **GTIN#:**
  - ✓ LP7 R3 – 00840682141314
  - ✓ LP9 R3 – 00840682141246

Product Description	HCAT #
Base Systems	
LOGIQ P7 R3	H42872LA
LOGIQ P9 R3	H42872LB
Probes	
3Sc-RS Probe	H45041DL
6S-RS PROBE	H45021RP
12S-RS Probe	H44901AB
ML6-15-RS Probe	H40462LM
L3-12-RS Probe	H44901AP
L4-12t-RS Probe	H48062AB
L12n-RS probe	H48062AH
12L-RS Probe	H40402LY
L6-12-RS Probe	H48062AC
9L-RS Probe	H40442LL
L10-22-RS Probe	H48312AH
L8-18i-RS Probe	H40462LF
C1-5-RS Probe	H40462LA
4C-RS Probe	H4000SR
8C-RS Probe	H40402LS
E8C-RS Probe	H40402LN
E8Cs-RS Probe	H48062AF
IC9-RS Probe	H48691PJ
BE9CS-RS Probe	H40482LN
RAB2-6-RS Probe	H48681WR
RIC5-9A-RS Probe	H48701EJ
6Tc-RS Probe	H45551ZE
Doppler P8D Probe	H46312LZ
P6D	H4830JG
P2D	H4830JE
L3-9i-RS Probe	H46442LK
Biopsy Options	
3SP MULTI-ANGLE BIOPSY	H46222LC
9L BIO GUIDE STARTER KIT	H4906BK
12L-RS Biopsy Starter Kit	H40432LC
ML6-15 Biopsy Starter Kit	H40432LJ
12L TRANSVERSE BRACKET	H48392LL
INFINITE 12L BIOPSY KIT	H48392LT

L3-12-D Biopsy starter kit	H48302AA
C1-5 Biopsy Starter Kit	H40432LE
4C BIOPSY BRACKET	E8385NA
E721 STARTER KIT	E8385MJ
E8C E721 E8C-RS IC5-9H MTZ Biopsy Kit	E8333JB
E8C REUSABLE BIOPSY KIT	H40412LN
BE9CS Biopsy Kit 742-339	H42742LH
BE9CS Biopsy Kit 742-401	H42742LJ
Reusable Biopsy Needle Guide for GE BE9C Ultrasound Probe	E8387MA
Sterile Disposable Biopsy Needle Guide Kit for GE BE9C Probe	E8387M
IC9 reusable Biopsy	H48701MN
IC9 Biopsy Starter Kit	H48691YW
RAB6-D BIOPSY STARTER KIT	H48681ML
PEC63 BIOPSY KIT FOR RIC5-9	H46721R
RIC STERILE NEEDLE GUIDE	H48681GF
TEE accessory	
TEE Cleaning and Storage System	H45551NK
TEE Storage Rack	H45551NM
TEE Scan Head Protection Cover	H45521CK
TEE Clip-on Bite Guard Adult	H45511EE
TEE Clip-on Bite Guard Adult OR	H45521CB
Conventional Bite Guard Adult	H45521JH
Bite Hole Indicator	H45531HS
Software options	
LP7 and LP9 Advanced 3D	H42782LK
LP7 and LP9 Auto IMT	H42782LL
LP7-P9 R3 HD B-Flow	H42892LR
LP7-P9 R3 CEUS	H42892LS
LP7-P9 R3 HRes CEUS	H42892LT
LP7 and LP9 DICOM	H42782LR
LP7 and LP9 Elastography	H42782LS
LP7 and LP9 Elastography Quantification	H42782LT
LP7 and LP9 Flow Quantification	H42782LW
LP7 and LP9 LOGIQView	H42782LY
LP7 and LP9 Report Writer	H42782LZ
LP7 and LP9 Scan Assistant	H42792LA
LP7 and LP9 Stress Echo	H42792LB
LP7 and LP9 Tissue Velocity Imaging TVI	H42792LC
LP7 and LP9 B Steer+	H42792LD
LP7 and LP9 4D TUI Software	H42792LF
LP7 and LP9 VOCAL Software	H42792LG
LP7 and LP9 VCI Static Software	H42792LH
LP7-P9 STIC	H42822LZ
LP7-P9 Omniview	H42832LA

LP7-P9 R3 HDLive	H42892LW
LP7 and LP9 Auto EF	H42792LJ
LP7 and LP9 Meas Assist Breast	H42792LK
LP7 and LP9 Meas Assist OB	H42792LL
LP7 and LP9 Breast Prod	H42792LM
LP7 and LP9 Compare Assistant	H42792LN
LP7 and LP9 Thyroid Prod	H42792LP
LP7 and LP9 SWDVR	H42792LR
LP7 MSK Korea	H42762LF
LP7-P9 Cardiac Strain	H42822LY
LP7-P9 R2.5 Pinpoint GT option	H40292LC
LP7-P9 R3 Shear Wave Elastography	H42892LY
LOGIQ P Apps	H42892LZ
LOGIQ P Apps without Dongle	H42922LM
LOGIQ P7 R3 Advanced Probes Convex	H42922LN
LOGIQ P7 R3 Advanced Probes Linear	H42922LP
LOGIQ P7 R3 Advanced Probes Sector	H42922LR
LOGIQ P7 R3 Advanced Probes Specialty	H42922LS
Hardware options	
LP7-P9 R3 Card Reader Mounting Kit	H42792LZ
Art. Monitor Arm white	H42902LB
LP7-P9 R3 Rear handle	H42902LC
LP7 and LP9 OPIO tray	H42802LG
LP7 and LP9 Paper tray	H42802LE
LP7 and LP9 Side Tray	H42802LC
LP7-P9 R3 Cable Hook rear	H42902LD
LP7-P9 R3 Gel Warmer	H42902LE
LP7-P9 R3 4 port kit	H42912LF
LP7 and LP9 4D Kit	H42802LD
LP7 P9 CW HW Kit	H46432LN
LP7 P9 Pencil CW HW Kit	H42802LB
USB FOOTSWITCH 3 BUTTON	H46732LF
LP7 P9 W. LESS LAN KIT-J	H42812LD
LP7 P9 W. LESS LAN KIT	H42802LL
LP7 P9 UVC	H42832LJ
LP7 P9 UVC for Japan	H42832LK
ISOLATION TRANSFORMER	H48671WN
Pwr supply noise filter	H46162LH
Pinpoint GT Practice kit	H48672AB
Barcode reader	H48872LG
LP7-P9 R3 ODD Option	H42912LE
ECG options	
LP7 P9 ECG module only	H42792LS
LS8 ECG CABLE - AHA	H46102LW

LS8 ECG CABLE - IEC	H45302LZ
Veterinary Use Only	
Vet kit	H46832LC
Probe Vet Label	H48992LR
Vet probe caution label	H48492AW
Peripherals	
Printers	
UP-D898 BW Printer Kit	H46992LS
LP7 LP9 BW INSTALL KIT	H46432LP
UP-D25MD PRINTER	H44642LW
Cabinet	
LP7-P9 R3 HIGH CABINET	H42902LG
LP7-P9 R3 DRAWER	H42902LH
LP7-P9 R3 Low Cabinet	H42902LJ
Accessories	
LP7-P9 R3 Multi P. holder	H42902LK
LOGIQ S7 R3 Small Probe Holder	H46302LB
PROBE CABLE HANGER	H44412LA
Batteries	
LP7-P9 R2 Battery option	H42832LG
LP7-P9 R3 ext battery	H42902LM
Power Cords	
POWER CORD FIX BRKT 220V	H42812LJ
POWER CORD FIX BRKT 110V	H42812LK
Destination Sets	
DESTINATION SET UK	H46712LM
DESTINATION SET S AFRICA	H46712LN
DESTINATION SET ARGENTINA	H46712LP
DESTINATION SET ISRAEL	H46712LR
DESTINATION SET SWISS	H46712LS
DESTINATION SET DENMARK	H46712LT
DESTINATION SET US	H46712LW
DESTINATION KIT AUS_NZ	H46712LZ
DESTINATION SET CHINA	H46722LA
DESTINATION SET INDIA	H46722LB
DESTINATION SET ITALY	H46722LD
DESTINATION SET BRAZIL	H46752LW
DESTINATION SET Taiwan	H44512LY
DESTINATION SET JAPAN	H46712LY
Keyboards and Key Cap Language Kits	
AN Keyb. Greek black	H42902LR
AN Keyb. Norwegian black	H42902LS
AN Keyb. Russian black	H42902LT
AN Keyb. French black	H42902LW

AN Keyb. Swedish black	H42902LY
AN Keyb. German black	H42902LZ
AN Keyb. English black	H42912LA
Upgrade kit	
LOGIQ P9 R2.5 to R3 SW conversion	H42922LK
LOGIQ P7 R2.5 to R3 SW conversion	H42922LL

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 P9 and LOGIQ P7 and included relevant information to users with the LOGIQ P9 and LOGIQ P7 instructions for use.

End of Document

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 075707 0078 Rev. 00

Manufacturer:

GE Healthcare Austria GmbH & Co OG
Tiefenbach 15
4871 Zipf
AUSTRIA

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713175299

Preceding certificate No.: this certificate is issued for the first time

Valid from: 2020-05-14
Valid until: 2025-05-13

Date of initial issuance / Rev.00: 2020-05-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-05-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 075707 0078 Rev. 00

Device Group	Risk Classification
Echographic Instruments	IIa

The validity of this certificate depends on conditions and/or is limited to the following:	None
Revision History including Changes:	00 / 2020-05-13 / 713175299

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-03-17
Certificate Registration No.:	SX 60146260 0001
An audit was performed. Report No.:	32090188 001
This Certificate is valid until:	2021-11-04

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-03-17

Balazs Bozsik

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60146260 0001
Report No.: 32090188 001

Organization: GE ULTRASOUND KOREA, Ltd.
9, Sunhwan-ro 214beon-gil, Jungwon-gu
SEONGNAM-SI, GYEONGGI-DO
Republic of Korea

Scope:

Design and Development, Manufacture and Final Test of Ultrasound Diagnostic Devices and Systems

Site Included:
GE Ultrasound Korea, Ltd.
65-1,Sangdaewon-dong, Jungwon-gu
Seongnami-si, Gyeonggi-do
462-120 Republic of Korea

Design and Development, Manufacture and Final Test of Ultrasound Diagnostic Devices and Systems

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-03-17

Balazs Bozsik