

# LOGIQ S7 XDclear 2.0



**Product Tree Europe**  
**Rev. 3**  
**Sep 30<sup>th</sup>, 2021**



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# System overview: LOGIQ S7 XDclear 2.0

## Probes:

- C1-6-D
- C2-9-D
- C3-10-D
- C2-7-D
- C1-5-D
- 10C-D
- C2-6b-D
- 9L-D
- ML6-15-D
- L8-18i-D
- 11L-D
- L3-12-D
- M5Sc-D
- M5S-D
- S4-10-D
- 3Sp-D
- S1-5-D
- 6S-D
- IC5-9-D
- BE9CS-D
- RAB6-D
- RIC5-9-D
- RSP6-16-D
- 6Tc-RS
- P2D
- P6D
- P8D

## SW Options:

- DICOM
- B-Flow
- B-Steer+
- LOGIQView
- Coded Contrast Imaging
- HiRes Contrast
- Parametric Imaging
- Shearwave Elastography
- Strain Elastography + QA
- Auto IMT
- Flow QA
- Thyroid / Breast Productivity
- Measure Assist Breast / OB
- Scan Assistant
- Compare Assistant
- TVI
- Cardiac AFI
- Stress Echo
- Auto EF
- DVR
- Report Writer
- Tricefy
- TUI
- VOCAL II
- STIC
- OmniView
- HDLive

## Care Area Packages:

- MSK Package
- Cardiac Package
- OB Package
- Breast Package

## HW Options:

- CW Doppler
- Pencil probe connector
- Realtime 4D
- Power Assistant
- Wireless LAN
- UVC

## ECG Options:

- ECG Kit
- ECG cable – IEC

## Printers:

- BW printer UP-D898DC
- Color printer UP-D25MD

## Accessories:

- Probe Holder Insert
- TV / TR probe holder
- Optional probe holder
- Probe cable hanger
- Footswitch – 3 buttons

## Veterinary Use:

- Veterinary Kit
- Probe Label Kit



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# Product Tree LOGIQ S7 XDclear 2.0

Item Number	Description	Description / Comments
	Base System	
H46512LH	LOGIQ S7 XDclear 2.0	<p>LOGIQ S7 XDclear 2.0. This comes with the following standard functions and features:</p> <ul style="list-style-type: none"> <li>• 23" LCD monitor</li> <li>• Universal Power Supply, EU power cord</li> <li>• Mid Cabinet, Gel Warmer</li> <li>• CrossXBeam</li> <li>• SRI</li> <li>• Advanced 3D</li> <li>• MyTrainer+</li> <li>• Enhanced Privacy &amp; Security (Enhanced password policy configurability, Session control &amp; Data Encryption)</li> <li>• eDoc CD, eIFU kit</li> </ul>



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Item Number	Description	Description / Comments
	<b>Power Cords and Destination Sets</b>	
	<b>Power Cords</b>	
H46712LM	DESTINATION SET UK	Additional Power Cord for UK
H46712LR	DESTINATION SET ISRAEL	Additional Power Cord for Israel
H46712LS	DESTINATION SET SWISS	Additional Power Cord for Switzerland
H46712LT	DESTINATION SET DENMARK	Additional Power Cord for Denmark
H46722LD	DESTINATION SET ITALY	Additional Power Cord for Italy
H46342LZ	Power Cord 220V for EU	Additional Power Cord for EU (for replacement only)
	<b>Keyboards and Key Cap Language Kits</b>	
H44922LW	AN key S10-8-6,Greek	Additional Key Cap for Greek
H44842LW	AN key S10-8-6,Norwegian	Additional Key Cap for Norwegian/Danish
H44842LY	AN key S10-8-6,Russian	Additional Key Cap for Russian
H44842LT	AN key S10-8-6,Swedish	Additional Key Cap for Swedish
H44852LB	AN key S10-8-6,German	Additional Key Cap for German
H44852LC	AN key S10-8-6,French	Additional Key Cap for French



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Item Number	Description	Description / Comments	Item Number	Description	Description / Comments
	<b>Manuals and Documentation</b>			<b>Manuals and Documentation</b>	
	<b>LOGIQ S7 Basic User Manual Hardcopy</b>			<b>LOGIQ S7 User Guide Hardcopy</b>	
H46232LB	LS7XD2 BUM - English	Basic User Manual Hardcopy - English	H46232LG	LS7XD2 UG - English	User Guide Hard Copy English
H46232LC	LS7XD2 BUM - French	Basic User Manual Hardcopy - French	H46232LH	LS7XD2 UG - French	User Guide Hard Copy French
H46232LD	LS7XD2 BUM - Spanish	Basic User Manual Hardcopy - Spanish	H46232LJ	LS7XD2 UG - Spanish	User Guide Hard Copy Spanish
H46232LE	LS7XD2 BUM - German	Basic User Manual Hardcopy - German	H46232LK	LS7XD2 UG - German	User Guide Hard Copy German
H46232LF	LS7XD2 BUM - Italian	Basic User Manual Hardcopy - Italian	H46232LL	LS7XD2 UG - Italian	User Guide Hard Copy Italian
	<b>LOGIQ S7 Advanced Reference Manual Hardcopy</b>		H46232LM	LS7XD2 UG - Dutch	User Guide Hard Copy Dutch
H46252LY	LS7XD2 ARM - English	Advanced Reference Manual Hard Copy - English	H46232LN	LS7XD2 UG - Estonian	User Guide Hard Copy Estonian
H46252LZ	LS7XD2 ARM - French	Advanced Reference Manual Hard Copy - French	H46232LP	LS7XD2 UG - Slovenian	User Guide Hard Copy Slovenian
	<b>Other Document</b>		H46232LR	LS7XD2 UG - Swedish	User Guide Hard Copy Sweedish
H4908LC	LOGIQ CLUB BOOKLET EUROPE		H46232LS	LS7XD2 UG - Polish	User Guide Hard Copy Polish
			H46232LT	LS7XD2 UG - Greek	User Guide Hard Copy Greek
			H46232LW	LS7XD2 UG - Hungarian	User Guide Hard Copy Hungarian
			H46232LY	LS7XD2 UG - Slovakian	User Guide Hard Copy Slovakian
			H46232LZ	LS7XD2 UG - Czech	User Guide Hard Copy Czeck
			H46252LH	LS7XD2 UG - Danish	User Guide Hard Copy Danish
			H46252LJ	LS7XD2 UG - Norwegian	User Guide Hard Copy Norwegian
			H46252LK	LS7XD2 UG - Finnish	User Guide Hard Copy Finnish
			H46252LL	LS7XD2 UG - Bulgarian	User Guide Hard Copy Bulgarian
			H46252LM	LS7XD2 UG - Romanian	User Guide Hard Copy Romanian
			H46252LN	LS7XD2 UG - Croatian	User Guide Hard Copy Croatian
			H46252LP	LS7XD2 UG - Lithuanian	User Guide Hard Copy Lithuanian
			H46252LR	LS7XD2 UG - Latvian	User Guide Hard Copy Latvian
			H46252LS	LS7XD2 UG - Serbian	User Guide Hard Copy Sebian
			H46252LT	LS7XD2 UG - Eu Portuguese	User Guide Hard Copy Eu Portuguese
			H46252LW	LS7XD2 UG - Ukrainian	User Guide Hard Copy Ukranian
			H46262LD	LS7XD2 UG - Kazakhstan	User Guide Hard Copy Kazakhstan

Note: Electronic Instructions for Use (eIFU) containing a leaflet with instructions translated into all languages and a USB Stick with all User Documentation are included with every system. These DOCs Kits are only needed if a customer requires a printed copy of the documents listed below (electronic versions of those are included in the eIFU).



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Item Number	Description	Description / Comments
	<b>2D XDclear Sector Phased Array</b>	
H44901AE	M5Sc-D	H46342LN (LS Advanced Probes) is required, for CWD H46482LH (CW Doppler Kit) is required
	<b>2D XDclear Curved Array</b>	
H40472LT	C1-6-D PROBE	H46342LN (LS Advanced Probes) is required
H40462LN	C2-9-D PROBE	H46342LN (LS Advanced Probes) is required
H40482LB	C3-10-D Probe	H46342LN (LS Advanced Probes) is required



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<b>2D Sector Phased Array</b>		
H45551NH	M5S- D	for CWD H46482LH (CW Doppler Kit) is required
H45302LA	S4-10-D TRANSDUCER	for CWD H46482LH (CW Doppler Kit) is required
H48681AZ	3SP-D PROBE	for CWD H46482LH (CW Doppler Kit) is required
H4913SD	S1-5-D Sector Transducer	
H45021RR	6S-DLP PHASE ARRAY PEDIATRIC PROBE	for CWD H46482LH (CW Doppler Kit) is required
<b>2D Linear Array</b>		
H40442LM	9L-D PROBE	
H40452LG	ML6-15-D PROBE	
H40452LL	L8-18I-D PROBE	
H40432LN	11L-D PROBE	
H48062AA	L3-12-D	
<b>2D Curved Array</b>		
H40452LE	C1-5-D PROBE	
H46342LA	10C-D Probe	
H46332LW	C2-6b-D Probe	
H46422LM	C2-7-D Probe	
<b>2D Endocavity</b>		
H40442LK	IC5-9-D PROBE	
H40482LE	BE9CS-D	
<b>4D Mechanical</b>		
H48681MG	RAB6-D PROBE	H46502LH (LS Real time 4D) is required
H48651MS	RIC5-9-D PROBE	H46502LH (LS Real time 4D) is required
H48651MR	RSP6-16-D 4D LINEAR ARRAY PROBE	H46502LH (LS Real time 4D) is required
<b>Intraoperative</b>		
H4915IO	L3-9i-D Transducer	
<b>Pencil</b>		
H4830JE	PENCIL PROBE P2D	Both H46482LH (CW Doppler Kit) and H45302LJ (Pencil CW HW Kit) are required
H4830JG	PENCIL PROBE P6D	Both H46482LH (CW Doppler Kit) and H45302LJ (Pencil CW HW Kit) are required
H46312LZ	Doppler P8D Probe	Both H46482LH (CW Doppler Kit) and H45302LJ (Pencil CW HW Kit) are required


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Item Number	Description	Description / Comments
<b>TEE Adult Probe</b>		
H45551ZE	6Tc-RS Multi-Plane TEE Probe	H46352LK (TEE RS-DLP Adapter) is required, for CWD H46482LH (CW Doppler Kit) is required
H46352LK	TEE RS-DLP Adapter	Required for H45551ZE 6Tc-RS TEE probe
<b>TEE Probe Accessories</b>		
H45551NK	TEE Cleaning and Storing System	For storage and automated cleaning of Adult and Pediatric TEE probes. Compact wall mounted solution for 4 stages: Enzymatic cleaning, Disinfection, Testing, Drying. Integrated and easy to use puncture testing.
H45551NM	TEE Storage Rack	Strongly recommended to order with the TEE probe For storage of Adult and Pediatric TEE probes, wall mounted unit. Store (and dry) disinfected probes, ready for the next use.
H45521CK	TEE Scanhead protection cover	
H45511EE	TEE Clip-on Bite Guard Adult	
H45521CB	TEE Clip-on Bite Guard Adult OR	
H45521JH	Conventional Bite Guard Adult	
H45531HS	Bite Hole Indicator	



TEE  
Cleaning  
System



TEE  
Storage  
Rack



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Item Number	Description	Description / Comments
<b>Biopsy Options 2D Sector Phased Array</b>		
H4908SD	S1-5 MLTI ANGLE BX STR KT	Non-sterile S1-5 multi-angle bracket
H4908ND	S1-5 V NAVIGATION BRACKET	Biopsy & Volume Navigation Sensor Brackets
<b>Biopsy Options 2D Linear Array</b>		
H4906BK	9L BIO GUIDE STARTER KIT	
H4908NB	9L VOL NAVIGATION BRACKET	Biopsy & Volume Navigation Sensor Brackets
H40432LJ	ML6-15 M_BIOPSY_SKIT	
H40432LK	ML6-15 M_BPSY_TRU3D_SKIT	Biopsy & Volume Navigation Sensor Brackets
H40432LC	12L-RS MULTI BIOPSY GUIDE	Non-sterile 11L, 11L-D, 12L-RS multi-angle bracket
H48302AA	L3-12-D Biopsy Kit	Non-sterile L3-12-D multi-angle bracket
<b>Biopsy Options 2D Curved Array</b>		
H4913BB	C1-6-D Biopsy Starter Kit	Non-sterile C1-6-D multi-angle bracket
H40432LE	C1-5 M_BIOPSY_ST_KIT	Non-sterile C1-5-D multi-angle bracket
H40432LF	C1-5 M_BIOPSY_TRU3D_SKIT	Biopsy & Volume Navigation Sensor Brackets
H4913BA	C2-9-D Biopsy Starter Kit	Non-sterile C2-9-D multi-angle bracket
H46332LY	C2-6b Needle Guide Pack	C2-6b Needle Guide Pack
H40482LK	C2-7 Biopsy Kit	C2-7 Biopsy Kit
H40482LL	C2-7 Biopsy Kit Stainless	C2-7 Biopsy Kit Stainless
<b>Biopsy Options 2D Endocavity</b>		
E8385MJ	E721 STARTER KIT	This Kit Contains 24 Disposable Biopsy Needle Guides
H40412LN	E8C REUSABLE BIOPSY KIT	One stainless steel single angle, reusable biopsy kit for E8CS/E8C/E721/IC5-9 transducers.
E8387M	Sterile Disposable Biopsy Guide Kit for GE BE9C	Disposable Biopsy Needle Guide Kit for the BE9C
E8387MA	Reusable Biopsy Guide for GE BE9C	Reusable Biopsy Guide for the GE BE9C Ultrasound Probe. Stainless steel allows repeat usage after sterilization requirements have been met per clinic or hospital protocol.
<b>Biopsy Options 4D</b>		
H46721R	PEC63 BIOPSY KIT FOR RIC5-9	Biopsy kit for RIC5-9-D
H48681ML	RAB6-D BIOPSY STARTER KIT	Biopsy kit for RAB4-D



## Product Tree LOGIQ S7 XDclear 2.0

Item Number	Description	Description / Comments
	<b>Care Area Packages</b>	
H46342MS	MSK Package	The MSK Package includes the following advanced tools: <ul style="list-style-type: none"> <li>• Shearwave Elastography</li> <li>• LOGIQView</li> <li>• B Steer+</li> <li>• Scan Assistant + Compare Assistant</li> </ul>
H46342CA	Cardiac Package	The Cardiac Package includes the following advanced tools: <ul style="list-style-type: none"> <li>• ECG Kit + ECG Cable – IEC style</li> <li>• Stress Echo</li> <li>• Auto EF</li> <li>• AFI Cardiac Strain</li> <li>• TVI</li> <li>• Auto IMT</li> <li>• Scan Assistant + Compare Assistant</li> </ul>
H46342OB	OB Package	The OB Package includes the following advanced tools: <ul style="list-style-type: none"> <li>• Realtime 4D Kit</li> <li>• Measure Assistant OB</li> <li>• HD Live</li> <li>• TUI</li> <li>• VCI-Static</li> <li>• VOCAL II</li> <li>• STIC &amp; OmniView</li> <li>• Scan Assistant + Compare Assistant</li> <li>• Tricefy</li> </ul>
H46342BR	Breast Package	The Breast Package includes the following advanced tools: <ul style="list-style-type: none"> <li>• Shearwave Elastography</li> <li>• Strain Elastography + Elasto QA</li> <li>• B Flow</li> <li>• Coded Contrast Imaging + HRes Contrast Upgrade</li> <li>• LOGIQView</li> <li>• Breast Productivity Package + Measure Assistant Breast</li> <li>• B Steer+</li> <li>• Scan Assistant + Compare Assistant</li> </ul>


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Item Number	Description	Description / Comments	Item Number	Description	Description / Comments
	<b>Software Options</b>			<b>Software Options</b>	
H46342LN	Advanced Probes	To enable XDclear probes		<b>Real Time 3D/4D</b>	
	Imaging		H46342LB	TUI	H46502LH (LS Real time 4D) is required to activate this item
H45342LC	B-FLOW		H46342LD	VCI-Static	H46502LH (LS Real time 4D) is required to activate this item
H46342LR	B Steer+		H46342LC	VOCAL_II	H46502LH (LS Real time 4D) is required to activate this item
H45342LK	LOGIQVIEW		H46502LD	STIC	H46502LH (LS Real time 4D) is required to activate this item
	<b>Connectivity</b>		H46502LE	Omni View	H46502LH (LS Real time 4D) is required to activate this item
H45342LF	DICOM		H46602LS	HD Live	H46502LH (LS Real time 4D) is required to activate this item
H46602LR	Tricify			<b>Cardiac applications</b>	
H45342LL	REPORT WRITER		H45342LP	TVI	
H46472LZ	Software DVR		H46342LF	Auto EF	ECG option H46572LR recommended
	<b>CEUS</b>		H46472LY	AFI Cardiac Strain	ECG option H46572LR recommended
H45342LT	HRES CONTRAST Upgrade	Requires H45342LD (Coded Contrast)	H45342LN	STRESS ECHO	ECG option H46572LR recommended
H45342LD	CODED CONTRAST			<b>Elastography</b>	
H46482LM	Parametric Imaging		H45342LG	Strain ELASTOGRAPHY	
	<b>Workflow / Productivity applications</b>		H45342LH	ELASTO QA	H45342LG Elastography option required
H45342LB	AUTO IMT		H46482LA	Shear Wave Elastography	
H45342LJ	FLOW QA				
H46342LK	Breast Productivity				
H46342LM	Thyroid Productivity				
H45342LM	SCAN ASSISTANT				
H46342LL	Compare Assistant				
H46342LH	Measure Assist Breast				
H46342LJ	Measure Assist OB				



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Item Number	Description	Description / Comments
	<b>Hardware Options</b>	
H46502LH	R4 Realtime 4D Kit	
H46482LH	R3 CW Doppler kit	Optional capability for CW examinations of vascular flow. Does not include probes, TVI, ECG module or cable.
H45302LJ	LS Pencil CW HW Kit	<b>H46482LH (R3 CW Doppler kit) is required</b>
H46572LW	Power Assistant Starter Kit	This parent HCAT contains the following items: H44832LK LS7 Power Assistant HW H46352LC Battery for Pow Assist
H46502LK	Power Assistant with Extended battery for scanning	This includes all necessary parts including battery to enables the One-hour Offline Scanning
	<b>ECG Options</b>	
H46572LR	LSR4 ECG Kit - no cable	ECG Module without cables.
H46102LZ	Ultrasound ECG cable (IEC)	ECG Cable Long Leads and Clips – IEC type cable
	<b>Cabinet</b>	
H44822LW	LOGIQ S High Cabinet	High cabinet option to support additional storage or peripherals.
H44822LY	LOGIQ S Mid Cabinet	Mid cabinet comes as standard. This option is for field upgrade from other cabinet option only.
H44822LZ	LOGIQ S Low Cabinet	Low cabinet optimizes system adjustability.
H46302LR	Side Cabinet for LOGIQ	Side cabinet that supports BW printer and Volume Navigation. This item is applicable only with H44822LY(LOGIQ S Mid Cabinet) or H44822LZ(LOGIQ S Low Cabinet)
H46262LF	Tray for Mid Cabinet	Storage tray to fit Mid Cabinet - This is for the "mid cabinet" systems only
H44832LA	Drawer	Drawer fits to Mid or High cabinet only



Product Tree LOGIQ S7 XDclear 2.0		
Item Number	Description	Description / Comments
	<b>Connectivity Options</b>	
H44932LH	WLAN A6210 USA and EU	Integrated wireless capability allows for wireless DICOM transfer within a 802.11ac/n/g/b/a wireless network
H46582LD	Universal Video Converter On Console Kit	This parent HCAT contains the following items: H46482LK UVC-S200 Kit H46502LM UVC On Bd Inst kit
H46482LW	Universal Video Converter Off Console Kit	This parent HCAT contains the following items: H46352LH UVC INST KIT OFF BOARD H46482LL LOGIQ S8 Off board UVC AC Adaptor
	<b>Peripherals</b>	
	<b>Printers</b>	
H46992LS	UP-D898 BW Printer Kit	Sony UP D898 digital B and W printer. Includes (1) roll Sony high resolution high gloss paper. H46302LM(LS7 R3 BW and Color Printer Installation Kit) should be ordered with this item
H44642LW	UP-D25MD PRINTER	Sony color thermal printer with USB connection H46302LM(LS7 R3 BW and Color Printer Installation Kit) should be ordered with this item
H46302LM	LS7 R3 BW and Color Printer Installation Kit	The printer installation kit. For LOGIQ S8. Only one kit required for both printer options.
	<b>Accessories</b>	
H46302LB	Small Probe Holder	Small Probe Adapter
H46732LF	USB Foot-switch - 3 Button	This is a 3-pedal footswitch with configurable button functionality at application level, providing the user with flexibility during procedures like stress echo requiring additional hand support.
H44412LA	Probe Cable Hanger	Probe cable hanger kit
H46542LP	TV/TR Probe Holder - white	Endocavity Probe Holder
H46292LY	Optional Probe Holder	Side probe holder. Additional holder for 2 probes. Attaches to front panel.
H46972LZ	Isolated USB connector	Isolated USB connector



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## Product Tree LOGIQ S7 XDclear 2.0

Item Number	Description	Description / Comments
	<b>Veterinary Labels</b>	
H46832LC	Vet kit	Labels and documents to make a LOGIQ console veterinary compliant
H48492AW	Vet probe caution label	Labels and documents to make a probe veterinary compliant (1 EA per probe), for Europe

### **Caution:**

For Veterinary use, dedicated VET Kits containing console and probe labels indicating that the system and probes are for veterinary use only must be ordered with the console and for each probe.

A dedicated 'VET Addendum' to the Basic User Manual is also included.

Labels will be applied to the console and probes by either the Make Center or the LPC before shipping the system/probes.

**It is not allowed to ship/install any system and probe for Veterinary usage not being labeled "For Veterinary Use Only"**

[System Overview](#)[Base System](#)[Power Cords, Destination Sets & Keyboards](#)[Manuals & Documentation](#)[XDclear Probes](#)[Probes](#)[TEE Adult Probe & Accessories](#)[Biopsy Guides](#)[Software Options](#)[Hardware Options](#)[Peripherals & Accessories](#)[Veterinary Use](#)[Revision History](#)

Rev.	Date	Author	Comment
1	Jan 24, 2020	J. Heimann	Initial Release
2	Mar 9, 2020	J. Heimann	New ECG cable on page 12: added H46102LZ, removed H45302LZ
3	Sep 30, 2021	J. Heimann	Added Care Area Packages (page 11)







## **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)

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**  
**78530 BUC, France**

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

Declare under our sole responsibility that the device:

**LOGIQ S7 XDclear2.0** including accessories and components  
Ref. See addendum  
GMDN Code: **40761**  
UDI-DI code: **LOGIQ S7 XDclear2.0/00840682146906**  
UMDNS Code: **15-976**  
Classification rule (93/42/EC Annex IX): **Rule 10, Class: IIa**

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

- The medical devices directive 93/42/EEC (MDD)
  - Technical documentation ref.: DOC2324384 / DHF ref.: DOC1800701, 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 SAS (Notified Body n° 0459)*, Certificate N °7697
  - List of harmonized standards applied on the product to which this declaration relates:
    - *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 (Edition 2.1)*
    - *EN 62304 : 2006 + A1: 2015*
    - *EN 62366-1 : 2015*
    - *EN ISO 15223-1: 2016*
    - *EN 1041 : 2008*



- The directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
  - Technical documentation ref.: DOC2324384 / DHF ref.: DOC1800701, of the product to which this declaration relates.
- The directive 2012/19/EU on the waste electrical and electronic equipment (WEEE)
  - Technical documentation ref.: DOC2324384 / DHF ref.: DOC1800701, of the product to which this declaration relates.
- The directive 2014/53/EU on the radio equipment (RED)
  - Technical documentation ref.: DOC2324384 / DHF ref.: DOC1800701, of the product to which this declaration relates.
- The Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices
  - Technical documentation ref.: DOC2324384 / DHF ref.: DOC1800701, of the product to which this declaration relates.

This EC declaration of conformity is the initial release.

  
\_\_\_\_\_  
Qingmeng Chen  
Product Regulatory Affairs Manager

*21-January-2020*  
Date: 21-January-2020



**ADDENDUM TO THE EC DECLARATION OF CONFORMITY**  
**dated 21-January-2020**

Product Description	Catalog Number <sup>1</sup>	Part Number <sup>2</sup>
<b>Ultrasound Console</b>		
LOGIQ S7 XDclear2.0	H46512LH	5836746
<b>Probes<sup>3</sup></b>		
C1-5-D Probe	H40452LE	5499513
3CRF-D Probe	H40462LK	5499603
IC5-9-D Probe	H40442LK	5499592
10C-D probe	H46342LA	5476030
C2-6b-D probe	H46332LW	5476026
C2-7-D Probe	H46422LM	5505700
BE9CS-D Probe	H40482LE	5535371
9L-D Probe	H40442LM	5499510
ML6-15-D Probe	H40452LG	5499600
L8-18i-D Probe	H40452LL	5499594
11L-D Probe	H40432LN	5499499
L3-12-D Probe	H48062AA	5482856
L3-9i-D Probe	H4915IO	5491310
M5S-D Probe	H45551NH	GE-R3MIX
S4-10-D Probe	H45302LA	5394804-2
3Sp-D Probe	H48681AZ	5561313
S1-5-D Probe	H4913SD	5438302-2
6S-D Probe	H45021RR	5499318
C2-9-D Probe (XDClear)	H40462LN	5499605
C1-6-D Probe (XDClear)	H40472LT	5499606
C3-10-D Probe (XDClear)	H40482LB	5493012
6Tc-RS Probe	H45551ZE	N/A
P2D Pencil Probe	H4830JE	TE100024
P6D Pencil Probe	H4830JG	TQ100002
P8D Doppler Probe	H46312LZ	5504447
RAB6-D Probe	H48681MG	KTZ303986
RIC5-9-D Probe	H48651MS	KTZ303987
RSP6-16-D Probe	H48651MR	KTZ303997
M5Sc-D Probe	H44901AE	5446030
C2-9VN-D PROBE	H40472LY	5488219
C1-6VN-D PROBE	H40472LW	5476279
C2-7VN-D Probe	H46422LN	5505701
<b>TEE Probe Accessories<sup>3</sup></b>		
TEE CLEANING SYSTEM	H45551NK	KX200168
TEE STORAGE RACK	H45551NM	KX200272
BITE HOLE INDICATOR	H45531HS	KZ200800
ADULT TEE CONVENTIONAL BITE GUARD	H45521JH	086A0016
ADULT TEE BITE GUARD, 25PCS.	H45551MR	086A0016
ADULT TEE CLIP-ON BITE GUARD	H45511EE	KZ200687
ADULT TEE CLIP-ON BITE GUARD, 25PCS.	H45551MM	KZ200687
ADULT TEE CLIP-ON BITE GUARD OPR.	H45521CB	KZ200693
ADULT TEE CLIP-ON BITE GUARD OR, 25PCS.	H45551MN	KZ200693
ADULT TEE SCANHEAD PROTECTION COVER	H45521CK	KZ307808
ADULT TEE SCANHEAD PROTECTION COVER, 25PCS.	H45551MS	KZ307808
PEDIATRIC TEE CONVENTIONAL BITE GUARD	H45521JG	086A0010
PEDIATRIC TEE BITE GUARD, 25PCS.	H45551MP	086A0010
PEDIATRIC TEE SCANHEAD PROTECTION	H45551MT	KZ307976



Product Description	Catalog Number <sup>1</sup>	Part Number <sup>2</sup>
COVER, 25PCS.		
PEDIATRIC TEE SCANHEAD PROTECTION COVER	H45541RN	KZ307976
<b>ECG Options<sup>3</sup></b>		
ECG Kit - no cable	H46572LR	5761966
External ECG cable	H45021DE	R2413451
ECG Cables IEC	H45302LZ	5341188
ECG Cable AHA	H45302LY	5341189
ECG Cable - AHA	H46102LW	5178978
<b>Biopsy Kits<sup>3</sup></b>		
9L-D Biopsy Starter Kit	H4906BK	5178413
C1-5-D Biopsy Starter Kit	H40432LE	5268272
ML6-15-D Biopsy Starter Kit	H40432LJ	5264178
IC5-9-D Disposable Biopsy Starter Kit	E8385MJ	N/A
IC5-9-D/E8C Reusable Biopsy Starter Kit	H40412LN	2398164
3CRF Biopsy Starter Kit - 13.1cm	H40442LR	5214870
3CRF Multiline Biopsy Starter Kit - 2.7 and 13.1cm	H40452LP	5214873
S1-5 Multi Angle Biopsy Starter Kit	H4908SD	5182579-21
C2-9-D Biopsy Starter Kit	H4913BA	5452714
12L-RS Biopsy Starter Kit	H40432LC	5176499
C2-6b Needle Guide Pack	H46332LY	5476028
C1-6-D Biopsy Starter Kit	H4913BB	5455207
C2-7 Biopsy Kit	H40482LK	5599259
C2-7 Biopsy Kit Stainless	H40482LL	5599260
L3-12-D Biopsy Kit	H48302AA	5487608
BE9C/BE9CS reusable	E8387MA	5479117
BE9C/BE9CS Disposal	E8387M	5479116
RIC5-9-D Biopsy kit	H46721R	N/A
RAB6-D Biopsy starter kit	H48681ML	N/A
RSP6-16-D Biopsy starter kit	H46701AD	KTI303231
<b>V-nav Options<sup>3</sup></b>		
9L-D V Nav Bracket Starter Kit	H4908NB	5391041
C1-5-D V Nav Bracket Starter Kit	H40432LF	5391411
ML6-15-D V Nav Bracket Starter Kit	H40432LK	5391412
S1-5 V Nav Bracket	H4908ND	5391042
S4-10 V NAV BRACKET	H4908NN	5363955-2
IC5-9 V NAV BRACKET	H4908NF	5363958-2
3CRF V NAV HOLDER SET	H40452LK	5357560
L8-18I V NAV BRACKET	H4908NH	5363959-2
M5S V NAV BRACKET	H4908NM	5396357
C2-9-D C1-6-D Vnav Brkt	H4913NK	5459116
C1-5 Vnav only bracket	H4913NL	5440200
C2-6b VNav Sensor Holder	H46332LZ	5476029
C2-7 Vnav Bracket Kit	H40482LM	5599261
C3-10 VNav Holder Starter Kit	H40482LF	5537710
3CRF V Nav Holder kit	H40482LH	5357560-2
R4 Vnav kit with SW key	H46542LR	5761962
R4 Needle Tracker kit SW key	H46542LS	5761964
VN probe option	H46542LT	5761965
VOLUME NAVIGATION STAND	H4908NS	5268740
V NAV NEEDLE TRACKING	H4910NT	5350924
VNav NT Storage Insert Kt	H4913NS	5447348
VNAV VIRTUAL NEEDLE TRKER	H4910NY	5350925
Virtual Tracker Sensor	H4911NG	5416625
VNav eTRAX 18-20g st kt	H4913NT	5451117
VNav eTRAX 12 14g st kt	H4913NU	5483528



Product Description	Catalog Number <sup>1</sup>	Part Number <sup>2</sup>
VNav eTRAX 14 16g st kt	H4913NV	5483544
VNav Active Tracker kit	H4913AT	5438658
VNav Probe Sensors	H4913PS	5168286-30
VNav MR Active Tracker	H4915MT	5670091
<b>Software Options</b>		
Auto IMT	H45342LB	5418120
B-Flow/B-Flow Color	H45342LC	5418121
HRES CONTRAST UPGRADE	H45342LT	5427609
Coded Contrast Imaging	H45342LD	5418122
CODED CONTRAST AM HRES	H46422LC	N/A
DICOM	H45342LF	5418124
Strain Elastography	H45342LG	5418125
Elasto QA	H45342LH	5418126
Flow QA	H45342LJ	5418127
LOGIQView	H45342LK	5418128
REPORT WRITER	H45342LL	5418131
Scan Assistant	H45342LM	5418132
Stress Echo	H45342LN	5418133
TVI (Tissue Velocity Imaging)	H45342LP	5418134
Advanced Probes	H46342LN	5477182
Auto EF	H46342LF	5477175
Breast Productivity Package	H46342LK	5477179
B-Steer+	H46342LR	5477184
Compare Assistant	H46342LL	5477180
Measure Assistant - Breast	H46342LH	5477177
Measure Assistant - OB	H46342LJ	5477178
Thyroid Productivity Package	H46342LM	5477181
TUI (Thomographic Ultrasound)	H46342LB	5477170
VCI-Static	H46342LD	5477172
VOCAL_II	H46342LC	5477171
Parametric Imaging	H46482LM	5477183
AFI Cardiac Strain	H46472LY	5669766
Software DVR	H46472LZ	5669767
Shear Wave Elastography	H46482LA	5669768
STIC	H46502LD	5761874
Omni View	H46502LE	5761876
Fibro Scan CAP	H46502LF	5761878
CAP for France	H46602LF	5794386
Tricefy	H46602LR	5817986
HD live	H46602LS	5817985
<b>Hardware Options<sup>3</sup></b>		
R4 Realtime 4D kit	H46502LH	5761956
Fibro/Extended battery HW upgrade for IB	H46502LJ	6063003-2
Pencil Probe CW HW Kit	H45302LJ	5418145
Power Assistant HW	H44832LK	5727565
FibroScan module	H46502LL	5761958
Battery for Pow Assist	H46352LC	5628196
Extended battery for scanning	H46502LK	5762182
R3 CW Doppler Kit	H46482LH	5669873
LOGIQ S HIGH CABINET	H44822LW	5727247
LOGIQ S MID CABINET	H44822LY	5727329
Tray for mid cabinet	H46262LF	5788538
LOGIQ S LOW CABINET	H44822LZ	5727248
R3 SIDE CABINET FOR LOGIQ	H46302LR	5746763
LOGIQ S DRAWER	H44832LA	5727254
Small probe holder	H46302LB	5727271



Product Description	Catalog Number <sup>1</sup>	Part Number <sup>2</sup>
WLAN A6210 USA and EU	H44932LH	5737412
UVC-S200 Kit	H46482LK	5669874
UVC On Board Install kit	H46502LM	5761959
UVC INST KIT OFF BOARD	H46352LH	5693947
LOGIQ S8 Off board UVC AC Adaptor	H46482LL	5589712
ACDC Adapter	Z72112FB	5589711
USB Foot Switch 3 button	H46732LF	5380960-2
PROBE CABLE HANGER	H44412LA	5165398
Sonazoid Key - white	H46542LN	5727489
TEE RS-DLP Adapter	H46352LK	5444874
Powervar144k120v MG UPS	H4913UP	5451390
TV/TR PRB HOLDER - white	H46542LP	5761961
Optional probe holder	H46292LY	5720392
BW and Color Printer Installation Kit	H46302LM	5727303
Isolated USB connector	H46972LZ	5507999
<b>Peripherals<sup>3</sup></b>		
UP-D898 BW Printer Kit	H46992LS	5599700
UP-D25MD PRINTER	H44642LW	5393211
REPORT PRINTER - INKJET	H4910RP	N/A
LOGIQ GI Inkjet Report Printer	H4914RP	5535186
LOGIQ Inkjet Report Printer	H4915RP	5716062
<b>Key Cap Language Kits</b>		
AN key S10-8-6,Greek	H44922LW	5722352
AN key S10-8-6,Norwegian	H44842LW	5722349
AN key S10-8-6,Swedish	H44842LT	5722348
AN key S10-8-6,French	H44852LC	5722343
AN key S10-8-6,German	H44852LB	5722342
<b>Destination Sets</b>		
DESTINATION SET UK	H46712LM	6736107-3
DESTINATION SET ISRAEL	H46712LR	6736109-3
DESTINATION SET SWISS	H46712LS	6736113-3
DESTINATION SET DENMARK	H46712LT	6736115-3
DESTINATION SET ITALY	H46722LD	6736110-3
Power Cord 220V for EU	H46342LZ	6736105-3
<b>Veterinary use</b>		
Vet kit	H46832LC	5604017

**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] Part number identifies the device(s) in the manufacturer's design, manufacturing and service documentation. It is usually affixed to the device(s) in the form of product identification or rating label.

[3] 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 S7 XDclear2.0 and included relevant information to users with the LOGIQ S7 XDclear2.0 instructions for use.

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End of Document

## **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 détails sur addendum / See attachment for additional information**

**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 : October 25th, 2019 (included)**

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



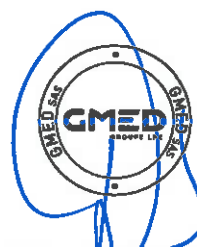
**Lionel DREUX**  
**Certification Director**



## Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P7	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ P9	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S8t	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON S10 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P6	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	VOLUSON P8	Ila

**GMED 0459**



**Lionel DREUX**  
 Certification Director



## Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S8	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Expert	Ila
Dispositif ou système de diagnostic par ultrasons <i>Ultrasound diagnostic device or system</i>	LOGIQ S7 Pro	Ila

12 alinéas / 12 indented lines.

## Identification du site couvert et des activités / Identification of location and activities

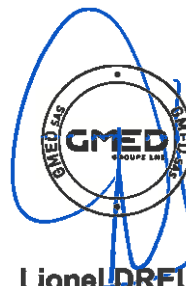
GE ULTRASOUND KOREA, Ltd. - 9, Sunhwan-ro 214beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do -  
REPUBLIC OF KOREA

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**



**Lionel DREUX**  
Certification Director



# Certificate

No. Q5 075707 0058 Rev. 02

**Holder of Certificate:** **GE Healthcare Austria GmbH & Co OG**  
Tiefenbach 15  
4871 Zipf  
AUSTRIA

**Facility(ies):** GE Healthcare Austria GmbH & Co OG  
Tiefenbach 15, 4871 Zipf, AUSTRIA  
  
Design and Development, Production  
and Distribution of Diagnostic Ultrasound  
Systems, Probes and Standalone Software  
for Ultrasound-Image Processing

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production  
and Distribution of Diagnostic Ultrasound  
Systems, Probes and Standalone Software  
for Ultrasound-Image Processing**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 075707 0058 Rev. 02)

**Report No.:** 713202497

**Valid from:** 2021-11-20  
**Valid until:** 2024-04-23

**Date,** 2021-11-11

Christoph Dicks  
Head of Certification/Notified Body

# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 14001:2015

Approval number(s): ISO 14001 – 0043295

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



001

# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Bulgaria LTD</b> Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Česká republika, s.r.o.</b> Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



001

# Certificate Schedule

Location	Activities
<b>GE Healthcare Danmark A/S</b> Park Allé 295, 2605 BRONDBY, Denmark	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare S.A.</b> 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Magyarország Kft.</b> Bence utca 3., 1138 BUDAPEST, Hungary	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Norge AS</b> Vitaminveien 1A, 0485 OSLO, Norway	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Polska Sp.z o.o.</b> ul. Woloska 9, 02-583 WARSAW, Poland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems SRL.</b> 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Holdings d.o.o.</b> Bulevar Mihaila Pupina 6/17 PC,, Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric International (Slovensko), s.r.o.</b> Prievozská 4, 821 09 BRATISLAVA, Slovakia	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelás 35-37, Urbanización La Florida, 28023 MADRID, Spain	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 14001:2015</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 45001:2018

Approval number(s): ISO 45001 – 00027009

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Bulgaria LTD</b> Dragan Tzankov Blvd. 36, World Trade Centre, 1040 SOFIA, Bulgaria	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Česká republika, s.r.o.</b> Bucharova 2641/14, Explora Business Centre, Jupiter Building, 158 00 PRAHA 5, Czech Republic	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare S.A.</b> 8-10 Sorou, Maroussi, 151 25 ATHENS, Greece	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Magyarország Kft.</b> Bence utca 3., 1138 BUDAPEST, Hungary	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Polska Sp.z o.o.</b> ul. Woloska 9, 02-583 WARSAW, Poland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. repair and installation of medical devices
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems SRL.</b> 301-311 Barbu Vacarescu St., District 2, Lakeview Building, 3rd floor, 020276 BUCHAREST, Romania	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Holdings d.o.o.</b> Bulevar Mihaila Pupina 6/17 PC., Usce, Novi Beograd, BELGRADE, 11070, Republic of Serbia	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management. associated with sales, marketing, services, repair and installation of medical devices



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# Certificate Schedule

Location	Activities
<b>General Electric International (Slovensko), s.r.o.</b> Prievozská 4, 821 09 BRATISLAVA, Slovakia	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelas 35-37, Urbanizacion La Florida, 28023 MADRID, Spain	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 45001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate of Approval

This is to certify that the Management System of:

## GE HEALTHCARE EUROPE SALES AND SERVICES

283 rue de la Minière, 78530 BUC, France

has been approved by Lloyd's Register to the following standards:

### ISO 50001:2018

Approval number(s): ISO 50001 – 0043293

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

#### The scope of this approval is applicable to:

Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



**Daniel Oliva Marcilio de Souza**

Area Operations Manager - South Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems SCS</b> 283 rue de la Minière, 78530 BUC, France	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GEMS SCS</b> 24 avenue de l'Europe, 78140 VELIZY VILLACOUBLAY, France	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare BVBA</b> Kouterveldstraat 20, Eagle Building, 1831 DIEGEM, Belgium	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Finland Oy</b> Kuortaneenkatu 2, 00510 HELSINKI 18, Finland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Information Technologies GmbH</b> Munzingerstr. 3a-5, 79111 FREIBURG, Germany	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices.
<b>GE Healthcare GmbH</b> Beethovenstr. 239, 42655 SOLINGEN, Germany	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Ireland Ltd</b> Unit F5, Centre Point Business Park, Oak Drive DUBLIN 12, Ireland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Italia SpA</b> Via Galeno 36, 20126 MILAN, Italy	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare Portugal, Sociedade Unipessoal, Lda.</b> Avenida do Forte 6 6-A, Ed. Ramazzotti, 2790-072 CARNAXIDE, Portugal	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare LLC</b> 10 Presnenskaya embankment, premise III, 12 floor, room 1, MOSCOW, 123112, Russian Federation	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Healthcare España, S.A.U</b> Calle Gobelás 35-37, Urbanización La Florida, 28023 MADRID, Spain	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Sverige AB</b> Vendevägen 89, 182 32 DANDERYD, Sweden	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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# Certificate Schedule

Location	Activities
<b>GE Medical Systems Schweiz AG</b> Europastrasse 31, 8152 GLATTBRUGG, Switzerland	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare</b> Pollards Wood, Nightingales Lane, Chalfont St Giles, HP8 4SP, Buckinghamshire, United Kingdom	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Medical Systems Nederland BV</b> De Wel 18, Building C, 3871 MV HOEVELAKEN, The Netherlands	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>General Electric Kazakhstan LLP</b> 308 of. "Grand-Alatau" Business Center, "Grand-Alatau" Business Center, Almaty, 050040, Kazakhstan	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.
<b>GE Healthcare Austria GmbH &amp; Co OG</b> Technologiestr. 10, 1220 WIEN, Austria	<b>ISO 50001:2018</b> Sales, delivery, installation, repairing, servicing, commissioning, and decommissioning of GE Healthcare medical devices and multivendor medical devices. Excluding office facility management.



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