

EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

We:

Manufacturer

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

Single Registration Number (SRN): AT-MF-000001461

Declare under our sole responsibility that the device:

Voluson Expert 22

Basic UDI-DI: 8406821BUG00148HD

Identification number (MD Number): 5805692

Intended Purpose:

The **Voluson Expert 22** is a general purpose ultrasound system intended for ultrasound image acquisition for diagnostic purposes incl. measurements on acquired image.

GMDN Code: 40761

GMDN Description: General-purpose ultrasound imaging system

Class: Ila

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis) and Rule 11 (Software) of Annex VIII of Council Regulation EU 2017/745]

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and the directive 2014/53/EU on the radio equipment (RED).

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Reference of the Declaration: DOC2530222



This conformity is based on the following elements:

- Technical Documentation reference: DOC2548733, of the product to which this declaration relates.
- EC certificate Number: G10 075707 0078
 - Conformity assessment procedure followed: Annex IX excluding Chapter II
 - Delivered by TÜV SÜD Product Service GmbH (Notified Body 0123), Ridlerstraße 65,80339
 Munich, Germany

This EC declaration of conformity supersedes the previous declaration dated 05-MAY-2022

SIGNATURE:

Date of issue:

09-JUN-2022

Place of issue:

Zipf/Austria

Name:

Roland Kuntscher

Function:

Regulatory Affairs Specialist

Signature:

REPUBLIC COMPANY OF THE PUBLIC COMPANY OF TH



ADDENDUM TO THE EC DECLARATION OF CONFORMITY

Product Description	Catalog Designation
Device, accessory description covered by this DoC and its associated technical documentation	Catalog number used by customer to order the device and/or accessories
Software Version: EC400	See Appendix A – List of Compatibility - Accessories and Options covered with this EC-DoC
Significance Letter: I	
Serial Number: From F160101 onwards + F60070 to F60099	See Appendix B – List of Compatibility used with Console Voluson Expert 22

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Appendix A:List of Compatibility -Accessories and Options covered by this EC-DoC

nsole Voluson Expert 22 EC400 (=Ref #)	Medical Device Number / Sales Number	
oluson Expert 22	5805692 (MD Number) / H48711KA (Cat. Number)	
Ipdate new VExpert SW	H48711NX (Cat. Number)	
eal Times 4D Probes		
AB6-D Volume Abdominal Probe	H48681MG ~	
IC5-9-D 5-9 MHZ 4D ENDOCAVITY PROBE	H48651MS <	
IC6-12-D 6-12MHz 4D ENDOCAVITY PROBE	H48651NA	
SP6-16-D; 6-16 MHz Realtime 4D broadband linear array probe	H48651MR ✓	
RM7C 4D Abdominal probe	5790293	
M6C G3 Volume Abdominal Probe	5835134 🗸	
RIC10-D 4D ENDOCAVITY PROBE	5845346	
oftware Options Individual		
Advanced VCI- Volume Contrast Imaging	H48681FP	
Advanced STIC	H48681GD *	
/CI-2D	N/A ~	
CODED CONTRAST IMAGING-CONTRAST MEDIA	H48681FT	
SonoAVC - Sono Automated Volume Count	H48681FX	
SonoVCADlabor	H48681FY <	
Elastography	H48681GB •	
Shear Wave Elastography	H48711EE -	
4DView 18 PC Software	H48701YF •	
V-SRI	H48711CY -	
E4D Advanced features	H48691YA -	
CW-Software Option	H48691NZ ·	
Tricefy Uplink	H48701NB ·	
IOTA (LR2, Simple Rules, Adnex)	N/A	
Fetal HQ	H48701WN 2	
Fetal HQ2	H48711PT 1	
Sono CNS	N/A ·	
Advanced Security Features	H48701WM >	
Premium Security Feature	H48701WT	
Voluson Remote Updates	H48711KH -	
SonoLyst	H48711NZ •	
SonoLyst live	N/A ·	
SonoPelvic Floor	H48711PA .	
Fetal HS	N/A a	
Adapt	N/A ·	
eDelivery	H48711NW ·	
AVURI Device Management (Permanent Access)	H48711PC ~	
Data Streaming	N/A ·	
Hardware Options		
	H48711KX ~	
ECG Digital Module USB	H48711KY	
ECG Digital Module USB (Canada) MDM400 monitor (OLED)	N/A ·	

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Appendix B: List of Compatibility used with Consoles Voluson Expert 22

Note: For this products GE Healthcare Austria GmbH & Co OG is not manufacturer

2D SMALL PARTS PROBES, LINEAR ARRAY	
11L-D linear array probe, small parts	H40432LN ^[1]
12L-RS Multi Biopsy Guide- CIVCO Part # 742-335	H40432LC ^[2] ^
9L-D linear array probe, small parts & vascular	H40442LM ^[1] *
Biopsy for 9L – CIVCO Part # 742-333	H4906BK ^[2]
ML6-15-D Active Matrix Phased Array Linear Probe	H40452LG ^[1] \
ML6-15D Biopsy Starter Kit, Multi-Angle - CIVCO Part # 742-352	H40432U ^[2] ,
L8-18i-D linear array probe, small parts	H40452LL ^{[1} •
2D ENDOCAVITY PROBES, MICRO-CURVED ARRAY	114043211:-
IC5-9-D endocavity probe	H40442LK ^[1] ,
Biopsy for IC5-9H, reusable	H40412LN ^[1]
Biopsy for IC5-9H, disposable (20) - CIVCO Part # 742-270	E8385MJ ^[2]
2D ABDOMINAL PROBES, CURVED ARRAY	EO292IVIJII
C2-9-D Curved Array Probe	H40462LN ^[1]
C2-9-D Biopsy Guide	H4913BA ^[2] ,
C1-6-D Curved Array Probe	
C1-6-D Biopsy Guide	H40472LT ^[1] -
D PHASED ARRAY PROBES	14313BBr-1 1
6S-D Phased Array Probe	H45021RR ^[3] ,
M5Sc-D Phased Array Probe	H44901AE3 -
M5Sc-D Biopsy Kit	H45561FC[2]
leal Times 4D Probes Biopsy Guides	143361FCF1 ,
RSP Biopsy Starter Kit - CIVCO Part # 742-327	H46701AD ^[2] }
RIC Biopsy PEC 63 - Reusable CIVCO	H46721R ^[2]
RIC Biopsy Starter Kit - Disposable CIVCO	H48681GF ^[2] '
AB6 Biopsy Starter Kit (RAB UltraLight) - CIVCO Part # 742-421	
0 , 21,00 rule 7+2-421	H48681ML ^[2] -

Notes:

- [1] EC-Declaration of Conformity by GE Healthcare Japan Corporation
- [2] EC-Declaration of Conformity by CIVCO Medical Solutions, USA
- [3] EC-Declaration of Conformity by GE Parallel Design, SAS France

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End of document

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