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: **IIa**

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).

Zipf, 09-JUN-2022

Roland Kuntscher
Regulatory Affairs Specialist

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:	

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

Zipf, 09-JUN-2022

Roland Kuntscher
Regulatory Affairs Specialist

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

Console Voluson Expert 22 EC400 (=Ref #)	Medical Device Number / Sales Number
Voluson Expert 22	5805692 (MD Number) / H48711KA (Cat. Number)
Update new VExpert SW	H48711NX (Cat. Number)
Real Times 4D Probes	
RAB6-D Volume Abdominal Probe	H48681MG
RIC5-9-D 5-9 MHZ 4D ENDOCAVITY PROBE	H48651MS
RIC6-12-D 6-12MHz 4D ENDOCAVITY PROBE	H48651NA
RSP6-16-D; 6-16 MHz Realtime 4D broadband linear array probe	H48651MR
RM7C 4D Abdominal probe	5790293
eM6C G3 Volume Abdominal Probe	5835134
RIC10-D 4D ENDOCAVITY PROBE	5845346
Software Options Individual	
Advanced VCI- Volume Contrast Imaging	H48681FP
Advanced STIC	H48681GD
VCI-2D	N/A
CODED CONTRAST IMAGING-CONTRAST MEDIA	H48681FT
SonoAVC - Sono Automated Volume Count	H48681FX
SonoVCAD*labor*	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
Fetal HQ2	H48711PT
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
Adapt	N/A
eDelivery	H48711NW
AVURI Device Management (Permanent Access)	H48711PC
Data Streaming	N/A
Hardware Options	
ECG Digital Module USB	H48711KX
ECG Digital Module USB (Canada)	H48711KY
MDM400 monitor (OLED)	N/A

Zipf, 09-JUN-2022

Roland Kuntscher
Regulatory Affairs Specialist

Reference of the Declaration: DOC2530222

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	H40432LJ[2]
L8-18i-D linear array probe, small parts	H40452LL[1
2D ENDOCAVITY PROBES, MICRO-CURVED ARRAY	
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	
C2-9-D Curved Array Probe	H40462LN[1]
C2-9-D Biopsy Guide	H4913BA[2]
C1-6-D Curved Array Probe	H40472LT[1]
C1-6-D Biopsy Guide	H4913BB[2]
2D PHASED ARRAY PROBES	
6S-D Phased Array Probe	H45021RR[3]
M5Sc-D Phased Array Probe	H44901AE[3]
M5Sc-D Biopsy Kit	H45561FC[2]
Real Times 4D Probes Biopsy Guides	
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]
RAB6 Biopsy Starter Kit (RAB UltraLight) - CIVCO Part # 742-421	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

Zipf, 09-JUN-2022

Roland Kuntscher
Regulatory Affairs Specialist

End of document