





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
<i>Device, accessory description covered by this DoC and its associated technical documentation</i>	<i>Catalog number used by customer to order the device and/or accessories</i>
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**

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)
<b>Real Times 4D Probes</b>	
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 ✓
<b>Software Options Individual</b>	
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 ✓
SonoVCADlabor	H48681FY ✓
Elastography	H48681GB ✓
Shear Wave Elastography	H48711EE ✓
4DView 18 PC Software	H48701YF ✓
V-SRI	H48711CY ✓
E4D Advanced features	H48691YA ✓
CW-Software Option	H48691NZ ✓
Tricify 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 ✓
<b>Hardware Options</b>	
ECG Digital Module USB	H48711KX ✓
ECG Digital Module USB (Canada)	H48711KY ✓
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

<b>2D SMALL PARTS PROBES, LINEAR ARRAY</b>	
11L-D linear array probe, small parts	H40432LN <sup>[1]</sup> ,
12L-RS Multi Biopsy Guide- CIVCO Part # 742-335	H40432LC <sup>[2]</sup> -
9L-D linear array probe, small parts & vascular	H40442LM <sup>[1]</sup> *
Biopsy for 9L - CIVCO Part # 742-333	H4906BK <sup>[2]</sup> ,
ML6-15-D Active Matrix Phased Array Linear Probe	H40452LG <sup>[1]</sup> \
ML6-15D Biopsy Starter Kit, Multi-Angle - CIVCO Part # 742-352	H40432LJ <sup>[2]</sup> ,
L8-18i-D linear array probe, small parts	H40452LL <sup>[1]</sup> •
<b>2D ENDOCAVITY PROBES, MICRO-CURVED ARRAY</b>	
IC5-9-D endocavity probe	H40442LK <sup>[1]</sup> \
Biopsy for IC5-9H, reusable	H40412LN <sup>[1]</sup> *
Biopsy for IC5-9H, disposable (20) - CIVCO Part # 742-270	E8385MJ <sup>[2]</sup> *
<b>2D ABDOMINAL PROBES, CURVED ARRAY</b>	
C2-9-D Curved Array Probe	H40462LN <sup>[1]</sup> *
C2-9-D Biopsy Guide	H4913BA <sup>[2]</sup> ,
C1-6-D Curved Array Probe	H40472LT <sup>[1]</sup> -
C1-6-D Biopsy Guide	H4913BB <sup>[2]</sup> r
<b>2D PHASED ARRAY PROBES</b>	
6S-D Phased Array Probe	H45021RR <sup>[3]</sup> ,
M5Sc-D Phased Array Probe	H44901AE <sup>[3]</sup> -
M5Sc-D Biopsy Kit	H45561FC <sup>[2]</sup> *
<b>Real Times 4D Probes Biopsy Guides</b>	
RSP Biopsy Starter Kit - CIVCO Part # 742-327	H46701AD <sup>[2]</sup> \
RIC Biopsy PEC 63 - Reusable CIVCO	H46721R <sup>[2]</sup> \
RIC Biopsy Starter Kit - Disposable CIVCO	H48681GF <sup>[2]</sup> \
RAB6 Biopsy Starter Kit (RAB UltraLight) - CIVCO Part # 742-421	H48681ML <sup>[2]</sup> -

- 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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