



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 18

Voluson Expert 20

Voluson Expert 22

Upgrade Kit: Voluson Exp to BT24 UPG

Model Version number: BT24

Basic UDI-DI: 8406821BUG00372HL

Identification number (MD Number): 5934554, 5934553, 5934552, 5936797

Intended Purpose:

The Voluson Expert 18, Voluson Expert 20, Voluson Expert 22 & Upgrade Kit for Voluson Expert 18/20/22 are general-purpose ultrasound systems or version upgrade kits for general-purpose ultrasound systems intended for ultrasound image acquisition for diagnostic purposes incl. measurements on acquired image.

EMDN Code: Z11040104

EMDN Description: MULTIDISCIPLINARY ULTRASOUND SCANNERS

GMDN Code: **40761**

GMDN Description: General-purpose ultrasound imaging system

Risk Class: **Ila**

Classification rule (Annex VIII): Rule 10 (Active MD for Diagnosis)



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, 20-Sep-2023

GE Healthcare Austria
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Thomas Reisenberger
Thomas Reisenberger
Sr. Regulatory Affairs Leader



This conformity is based on the following elements:

- Technical Documentation reference: DOC2824421, 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



GE Healthcare Austria
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 Tiefenbach 15
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Signature:			
Name:	Thomas Reisenberger	Function:	Sr. Regulatory Affairs Leader
Date of Issue:	20-Sep-2023	Place of Issue:	Zipf, Austria

This EC declaration of conformity supersedes the previous declaration dated 11-Sep-2023
 Document valid until 13-May-2025



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>Sales number used by customer to order the device and/or accessories</i>
Software Version: SW EC410 Ext.0 B	Cat# H48711UD Voluson Exp to BT24 UPG MD# 5936797 Voluson Exp to BT24 UPG
Voluson Expert 18 BT24:	Cat# H48711UB ^[A] MD# 5934554 ^[B]
Voluson Expert 20 BT24:	Cat# H48711UA ^[A] MD# 5934553 ^[B]
Voluson Expert 22 BT24:	Cat# H48711TZ ^[A] MD# 5934552 ^[B]
Voluson Exp to BT24 UPG	Cat# H48711UD ^[A] MD# 5936797 ^[B]

^[A]..... Cat # identifies the device(s) in the manufacturer’s catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.

^[B]..... Medical Device number (MD#) identifies the device(s) in the manufacturer’s design and manufacturing.

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

		Voluson Expert 18	Voluson Expert 20	Voluson Expert 22
Console (= Ref #)	Medical Device Number (MD) ^[B] / Sales Number (Cat) ^[A]			
Voluson Expert 18 BT24	MD# 5934554 / Cat# H48711UB	X	-	-
Voluson Expert 20 BT24	MD# 5934553 / Cat# H48711UA	-	X	-
Voluson Expert 22 BT24	MD# 5934552 / Cat# H48711TZ	-	-	X
Voluson Exp to BT24 UPG	MD# 5936797 / Cat# H48711UD	X	X	X
Real Times 4D Probes				
RAB6-D Volume Abdominal Probe	H48681MG	X	X	X
RIC5-9-D 5-9 MHZ 4D ENDOCAVITY PROBE	H48651MS	X	X	X
RIC6-12-D 6-12MHz 4D ENDOCAVITY PROBE	H48651NA	-	-	X
RSP6-16-D; 6-16 MHz Realtime 4D broadband linear array probe	H48651MR	X	X	X
RM7C 4D Abdominal probe	5790293	-	X	X
eM6C G3 Volume Abdominal Probe	5835134	-	-	X
RIC10-D 4D ENDOCAVITY PROBE	5845346	X	X	X
RIC12-D 4D ENDOCAVITY PROBE	5918580	-	-	X
Software Options Individual				
4DView 18 PC Software	H48701YF	X	X	X
Advanced Security Features	H48701WM	X	X	X
Advanced STIC	H48681GD	X	X	X
Advanced VCI- Volume Contrast Imaging	H48681FP	X	X	X
AVURI Device Management (Permanent Access)	H48711PC	X	X	X
CODED CONTRAST IMAGING-CONTRAST MEDIA	H48681FT	X	X	X
Curved Matrix Activation	H48711UH	-	X	X
CW-Software Option	H48691NZ	X	X	X
Data Streaming	N/A	X	X	X
eDelivery	H48711UEED	X	X	X
Elastography	H48681GB	X	X	X
Fetal HQ2	H48711PT	-	X	X
Fetal HS	N/A	X	X	X



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HDLive Studio	H48711WW	-	X	X
HDLive Silhouette	H48701WU	X	X	-
IOTA (LR2, Simple Rules, Adnex)	N/A	X	X	X
Maternal Ophthalmic Artery	H48711UK	X	X	X
Premium Security Feature	H48701WT	X	X	X
RadiantFlow	H48711ED	X	X	X
Shear Wave Elastography	H48711EE	X	X	X
Sono CNS	N/A	X	X	X
SonoAVC - Sono Automated Volume Count	H48681FX	X	X	X
SonoGyn	H48711UL	X	X	X
SonoLyst 1st Trim	N/A	X	X	X
SonoLyst	H48711NZ	X	X	X
SonoLyst live	H48711UN	X	X	X
SonoLyst IR/X/Live	H48711XG	X	X	X
SonoPelvic Floor	H48711PA	X	X	X
SonoPelvic Floor 2.0	H48711UM	X	X	X
SonoVCADlabor	H48681FY	X	X	X
Tricefy Uplink	H48701NB	X	X	X
Voluson Remote Updates	H48711KH	X	X	X
V-SRI	H48711CY	X	X	X
e4D Advanced Features	H48691YA	-	-	X
Forte Performance	H48711NY	-	-	X
Hardware Options				
ECG Digital Module USB	H48711KX	X	X	X
ECG Digital Module USB (Canada)	H48711KY	X	X	X

X...available for this type of Console

Notes:

- [A].... Cat # identifies the device(s) in the manufacturer's catalog and is usually included on commercial documents like sale contract, order processing documents and shipping documents.
- [B].... Medical Device number (MD#) identifies the device(s) in the manufacturer's design and manufacturing.



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Appendix B: List of Configurable Items

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

		Voluson Expert 18	Voluson Expert 20	Voluson Expert 22
2D SMALL PARTS PROBES, LINEAR ARRAY				
11L-D linear array probe, small parts	H40432LN ^[1]	X	X	X
12L-RS Multi Biopsy Guide- CIVCO Part # 742-335	H40432LC ^[2]	X	X	X
9L-D linear array probe, small parts & vascular	H40442LM ^[1]	X	X	X
Biopsy for 9L – CIVCO Part # 742-333	H4906BK ^[2]	X	X	X
ML6-15-D Active Matrix Phased Array Linear Probe	H40452LG ^[1]	X	X	X
ML6-15D Biopsy Starter Kit, Multi-Angle - CIVCO Part # 742-352	H40432LJ ^[2]	X	X	X
L8-18i-D linear array probe, small parts	H40452LL ^[1]	X	X	X
2D ENDOCAVITY PROBES, MICRO-CURVED ARRAY				
IC5-9-D endocavity probe	H40442LK ^[1]	X	X	X
Biopsy for IC5-9H, reusable	H40412LN ^[1]	X	X	X
Biopsy for IC5-9H, disposable (20)	E8385MJ ^[2]	X	X	X
2D ABDOMINAL PROBES, CURVED ARRAY				
C2-9-D Curved Array Probe	H40462LN ^[1]	X	X	X
C2-9-D Biopsy Guide	H4913BA ^[2]	X	X	X
C1-6-D Curved Array Probe	H40472LT ^[1]	X	X	X
C1-6-D Biopsy Guide	H4913BB ^[2]	X	X	X
2D PHASED ARRAY PROBES				
6S-D Phased Array Probe	H45021RR ^[3]	X	X	X
M5Sc-D Phased Array Probe	H44901AE ^[3]	X	X	X
M5Sc-D Biopsy Kit	H45561FC ^[2]	X	X	X
2D PHASED ARRAY PROBES				
RAB7-D Volume Abdominal Probe	H48062AN	X	X	X
Real Times 4D Probes Biopsy Guides				
RSP Biopsy Starter Kit - CIVCO Part # 742-327	H46701AD ^[2]	X	X	X
RIC Biopsy PEC 63 - Reusable CIVCO	H46721R ^[2]	X	X	X
RIC Biopsy Starter Kit - Disposable CIVCO	H48681GF ^[2]	X	X	X
RAB6 Biopsy Starter Kit - CIVCO Part # 742-421	H48681ML ^[2]	X	X	X
RIC10-D Biopsy – Disposable CIVCO	H44901AW ^[2]	X	X	X
RIC10-D Biopsy – Disposable Set CIVCO	H44901AX ^[2]	X	X	X
RIC10-D Biopsy – reusable CIVCO	H44901AY ^[2]	X	X	X

X...available for this type of Console

- 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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