



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): TBD

Declare under our sole responsibility that the device:

Voluson E10

Upgrade Kits:

VE-Series BT20 to BT21

Update to new VE-Series BT21 SW

Basic UDI-DI: 8406821BUG00012GK

Identification number (MD-Number):

Voluson E10: 5838786 , Upgrade-Kit VE-Series BT20 to BT21: 5538954

Update to new VE-Series BT21 SW: 5750715

Intended Purpose:

The **Voluson E10** 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).

Zipf, 07-OCT-2020


Roland Kuntscher
Regulatory Affairs Specialist



This conformity is based on the following elements:

- Technical Documentation reference: **DOC2422071**, of the product to which this declaration relates.
- EC certificate Number: **G10 075707 0078 Rev.00**
 - Conformity assessment procedure followed: Annex IX excluding Chapter II
 - Delivered by **TÜV SÜD Product Service GmbH** (Notified Body **0123**), Ridlerstraße 65, 80339 Munich, Germany
- List of common specifications applied and in relation to which conformity is declared:

Harmonized Standards:

- **EN 60601-1:2006 +A1:2013** (General safety requirements for medical products)
- **EN 60601-1-2:2015** (EMC requirements for medical products)
- **EN 60601-1-6:2010** (Usability requirements for medical products)
- **EN 62366 :2008** (Application of usability engineering to medical devices)
- **EN 60601-2-37:2008** (Particular requirements for ultrasonic medical products)
- **EN62304:2006+C1:2008** (Medical Device Software- Software Life Cycle Processes)

This EC declaration of conformity supersedes the previous declaration dated 25-Sep-2020

SIGNATURE:

Date of issue: 07-OCT-2020
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: EC360	See Appendix A – List of Compatibility - Accessories and Options covered with this EC-DoC
Significance Letter: B	
Serial Number: starting with E78001	See Appendix B – List of Compatibility used with Console Voluson E10

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

Console Voluson E10 EC360	Ref #
Voluson E10 BT21	5838786 (MD Number) / H48711LC (Cat. Number)
Voluson E10 BT21 OLED	5838786 (MD Number) / H48711LA (Cat. Number)
Upgr VE-series BT20 to BT21	5538954 (MD Number) / H48711LH (Cat. Number)
Update new VE BT21 SW	5750715 (MD Number) / H48711LJ (Cat. Number)
Real Times 4D Probes	
RAB6-D Volume Abdominal Probe	H48681MG
RAB2-5-D Volume Abdominal Probe	H48651MN
RIC5-9-D 5-9 MHZ 4D ENDOCAVITY PROBE	H48651MS
RIC6-12-D 6-12MHZ 4D ENDOCAVITY PROBE	H48651NA
RM6C 4D AMA Abdominal probe	H48671ZG
RSP6-16-D; 6-16 MHz Realtime 4D broadband linear array probe	H48651MR
eM6C Volume Abdominal Probe	H48681MJ
eM6C G2 Volume Abdominal Probe	H48701ES
RM7C 4D Abdominal probe	5790293
eM6C G3 Volume Abdominal Probe	5835134
Software Options Individual	
Advanced 4D	H48681FM
VOLUME CALCULATION II (VOCAL)	H48681FN
Advanced VCI- Volume Contrast Imaging	H48681FP
Anatomical M-Mode	H48681FZ
CODED CONTRAST IMAGING-CONTRAST MEDIA	H48681FT
Advanced STIC	H48681GD
SonoAVC - Sono Automated Volume Count	H48681FX
SonoVCADlabor	H48681FY
Elastography	H48681GB
Shear Wave Elastography	H48711EE
4DView 17 PC Software	H48701RL
4DView 18 PC Software	H48701YF
V-SRI	H48711CY
DVD & USB Recorder	H48701WR
E4D Advanced features	H48691YA
CW-Software Option	H48691NZ
Tricify Uplink	H48701NB
IOTA LR2	5537951
IOTA Simple Rules	H48701WP
Fetal HQ	H48701WN
Fetal HQ2	H48711NF
Advanced Security Features	H48701WM
Premium Security Feature	H48701WT
IDEA	5824725
IOTA Adnex	H48711EG
Voluson Remote Updates	H48711KH
Hardware Options	
ECG Digital Module	H48691LN
OLED Monitor	H48701EC
23" LCD Monitor High Megazone	H48711NK

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**Appendix B: List of Compatibility used with Consoles Voluson E10**

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 ^[4]
9L-D linear array probe, small parts & vascular	H40442LM ^[1]
Biopsy for 9L - CIVCO Part # 742-333	H4906BK ^[4]
ML6-15-D Active Matrix Phased Array Linear Probe	H40452LG ^[1]
ML6-15D Biopsy Starter Kit, Multi-Angle - CIVCO Part # 742-352	H40432LJ ^[4]
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 ^[4]
2D ABDOMINAL PROBES, CURVED ARRAY	
4C-D Curved Array Probe, Abdominal and OB/Gyn	H4001BC ^[2]
4C General Purpose Multi Angle Bracket - CIVCO Part #742-323	E8385NA ^[4]
C1-5-D Curved Array Probe	H40452LE ^[1]
Biopsy guide C1-5-D - CIVCO Part # 742-357	H40432LE ^[4]
C4-8-D Curved Array Probe	H48681AS ^[2]
Biopsy for C4-8-D - CIVCO Part # 742-390	H48681AT ^[4]
C2-9-D Curved Array Probe	H40462LN ^[1]
C2-9-D Biopsy Guide	H4913BA ^[4]
C1-6-D Curved Array Probe	H40472LT ^[1]
C1-6-D Biopsy Guide	H4913BB ^[4]
2D PHASED ARRAY PROBES	
3Sp-D Phased Array Probe	H48681AZ ^[3]
3Sp Multi-angle Biopsy - CIVCO Part # 742-370	H46222LC ^[4]
S4-10-D Phased Array Probe	H45302LA ^[5]
M5Sc-D Phased Array Probe	H44901AE ^[6]
M5Sc-D Biopsy Kit	H45561FC ^[4]
Real Times 4D Probes Biopsy Guides	
RAB Biopsy Starter Kit - CIVCO Part # 742-325	H46701AE ^[4]
RSP Biopsy Starter Kit - CIVCO Part # 742-327	H46701AD ^[4]
RIC Biopsy PEC 63 - Reusable CIVCO	H46721R ^[4]
RIC Biopsy Starter Kit - Disposable CIVCO	H48681GF ^[4]
RAB6 Biopsy Starter Kit (RAB UltraLight) - CIVCO Part # 742-421	H48681ML ^[4]
eM6C Biopsy Starter Kit - CIVCO Part # 742-374	H48681MK ^[4]
eM6CG2 Biopsy Starter Kit - CIVCO Part #	H48701MP ^[4]

- Notes: [1] EC-Declaration of Conformity by GE Healthcare Japan Corporation
[2] EC-Declaration of Conformity by GE Parallel Design, Inc. USA
[3] EC-Declaration of Conformity by Humanscan, Korea
[4] EC-Declaration of Conformity by CIVCO Medical Solutions, USA
[5] EC-Declaration of Conformity by GE Medical Systems & Primary Care Diagnostics, LLC, USA
[6] EC-Declaration of Conformity by GE Parallel Design, SAS France

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