



## DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II  
and of the directive 2011/65/EU, and of the directive 2014/53/EU

We

Manufacturer

**GE Medical Systems (China) Co., Ltd.**  
**No. 19, Changjiang Road**  
**WuXi National Hi-Tech Dev. Zone**  
**214028 Jiangsu China**

EU Authorized Representative

**GE Medical Systems SCS**  
**283 rue de la Minière**  
**78530 BUC, France**

Declare under our sole responsibility that the device:

### **Versana Balance**

Ultrasound system, imaging, general-purpose

Ref: see addendum

GMDN Code: **40761**

Classification rule (93/42/EEC Annex IX): **10**      **Class IIa**

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which 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.

Wuxi, 14-August-2019

Gao, Gan      *Gao Gan*  
Lead Engineer, Safety and Regulatory

This is the first EC declaration of conformity for Versana Balance.



This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: **DOC2286667/ DOC2097186**, of the product to which this declaration relates
  - EC Certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by **TÜV Rheinland LGA Products GmbH** (Notified Body 0197) / Certificate N HD 60116081 0001
  - harmonized standards applied on the product to which this declaration relates
    - EN 60601-1:2006+A1:2013+A11:2011+A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances- Requirements and tests
    - EN 60601-1-6:2010+ A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - EN 60601-2-37:2008+A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
    - EN 62366:2008 + A1:2015 Medical devices - Application of usability engineering to medical devices
    - EN 62304:2006 + A1:2015 Medical device software - Software life-cycle processes
    - EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
    - EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: **DOC2285657/ DOC2097186**, of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical Documentation/DHF Ref./ réf: **DOC2286667/ DOC2097186**, of the product to which this declaration relates
  - harmonized standards applied on the product to which this declaration relates:
    - Health & Safety (Directive 2014/53/EU Art. 3(1)(a)): EN 60601-1:2006+A1:2013+A11:2011+A12:2014 per Directive 93/42/EEC;
    - EMC (Directive 2014/53/EU Art.3(1)(b)): EN 60601-1-2: 2015 per Directive 93/42/EEC;
    - Radio Spectrum (Directive 2014/53/EU Art.3(2)): EN 300 328 v 2.1.1 (2016-11); EN 301 893 V 2.1.1 (2017-05) -as declared in DOC2007709.

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**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2286667**  
**Versana Balance configurations - Consoles and Options**

CONSOLE Name with description	GEHC Part <sup>[1]</sup>	REF # <sup>[2]</sup>	GEHC Cat # <sup>[3]</sup>
Versana Balance	5808534	Versana Balance VS	H48302BA
Versana Balance	5808536	Versana Balance VA	H48302BB
Versana Balance	5808536	Versana Balance VA	H48302BC
Console options <sup>[4]</sup>		GEHC Cat # <sup>[3]</sup>	
VSN B Scan Coach			H48302BP
VSN B SonoBiometry			H48302BR
VSN B TVI			H48302BG
VSN B Auto IMT			H48302BT
VSN B AMM			H48302BF
VSN B Easy/Adv_3D			H48302BZ
VSN B LOGIQ View			H48302BJ
VSN B DICOM			H48302BD
VSN B CWD			H48302BE
VSN B Needle rec			H48302BK
VSN B B-Flow™			H48302BH
VSN B AutoEF			H48302BS
VSN B Follow-up Tool			H48302BN
VSN B Thyroid productivity			H48302BY
VSN B Tricefy			H48312BB
VSN B Auto Bladder			H48302BW
VSN B Stress Echo			H48302BL
VSN A BreastCare			H48302BM
VSN B 4D software			H48312BA
CWD Hardware Option			H48102BM
4D Hardware			H48172BW
Battery charger			H48342BM
Battery			H48772AT
EMI Filter			H48242BD
Power box external grounding cable			H48342BS
Isolation USB for AC printer			H48242BC
Gel Warmer			H48342BW
Paper tray			H48322BC
VSN B Printer shelf			H48342BN
VSN B Cable for UP-D898DC Printer			H48342BP

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**Versana Balance – Probes and Accessories**

Probes and Accessories <sup>[5]</sup>	TYPE <sup>[6]</sup>	GEHC Cat # <sup>[3]</sup>
4C-RS probe	BF	H4000SR
L6-12-RS probe	BF	H48062AC
3Sc-RS probe	BF	H45041DL
8C-RS probe	BF	H40402LS
E8C-RS probe	BF	H40402LN
E8Cs-RS probe	BF	H48062AF
6S-RS probe	BF	H45021RP
12L-RS probe	BF	H40402LY
LK760-RS probe	BF	H44901AF
RAB2-6-RS probe	BF	H48681WR
4C-RS Biopsy Kit	N/A	E8385NA
L6-12-RS Biopsy Kit	N/A	H40432LC
3Sc-RS Biopsy Kit	N/A	H46222LC
RAB2-6-RS Biopsy Kit	N/A	H48681ML
E8C-RS Biopsy Kit	N/A	E8385MJ
E8C-RS Reusable Biopsy Kit	N/A	H40412LN
12L Transverse bracket	N/A	H48392LL
Infinite 12L biopsy kit	N/A	H48392LT

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**Versana Balance – Peripherals**

Accessories <sup>[5]</sup>	GEHC Cat # <sup>[3]</sup>
SONY UPD25 Color Printer USA Kit	H48542LZ
SONY UPD25 Color Printer EUP Kit	H48552LA
SONY UPD25 Color Printer CHN Kit	H48542LY
SONY UPD25 Color Printer JPN Kit	H48552LB
SONY UPD25 Color Printer Brazil Kit	H48312AN
BW PRINTER (UP-D898MD)	H48492AZ
UP-D898DC Printer	H48052BG
898 printer paper	H41402LS
Footswitch MKF 2-MED USB GP26	H41642LS
1-Peadl type footswitch 'Whanam FSU-1000'	H41882LD
USB Stick	H48442BK
1TB mobile USB HDD	H48492AB
Transcend TS8XDVDS-K DVDRW	H48312BJ
USB ECG Module (IEC)-MFG Germany	H48502AR
USB ECG Module (AHA)-MFG Israel	H41852LK
USB ECG Module (IEC)-MFG Israel	H41852LL
ECG ASSY w/ Chinese Label	H41852LM
Wireless Adaptor	H48832AC

**Versana Balance – Vet Options**

Vet Consoles and Options	GEHC Cat # <sup>[3]</sup>
VSN B SW option for Vet body marks	H48312BC
VSN B Vet kits	H48312BR
Vet probe caution label	H48992LR
Vet probe caution label	H48492AW

Notes used in the tables :

- <sup>1</sup> **GEHC Part #** identifies the device(s) in the manufacturer's design, manufacturing and service documentation.
- <sup>2</sup> **REF #** is usually affixed to the device(s) in the form of a product identification or model on the rating label.
- <sup>3</sup> **GEHC 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.
- <sup>4</sup> **Console options** are not CE marked in their own right, but covered by the CE mark of Versana Balance
- <sup>5</sup> **Probes, Accessories and Peripherals** may carry the CE-mark and, when applicable, the Notified Body number corresponding to the EC Declaration under which the products are CE-marked by their manufacturer.  
GE Medical Systems (China) Co., Ltd. has verified the mutual compatibility of the devices in combination with Versana Balance and included relevant information to users with the Versana Balance instructions for use. This activity was subject to appropriate methods of internal control and inspection.
- <sup>6</sup> **Type** identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

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