



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 Active

Ultrasound system, imaging, general-purpose

Ref: see addendum

GMDN Code: **40761**

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

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, 10-February-2020

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

This EC declaration of conformity supersedes the previous declaration dated 23-Oct-2019



This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
 - Technical Documentation/DHF Ref./ réf: **DOC2285657/ 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 60145949 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: **DOC2285657/ 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); EN301 893 v2.1.1 (2017-05) - as declared in DOC2007709.

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**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2285658****Versana Active configurations – Consoles and Options**

CONSOLE Name with description	GEHC Part ^[1]	REF # ^[2]	GEHC Cat # ^[3]
VSN Active	5808541	Versana Active	H48402BA
VSN Active with 1T SSD	5808541	Versana Active	H48412BP
Console options ^[4]		GEHC Cat # ^[3]	
VSN A Scan Coach		H48402BP	
VSN A SonoBiometry		H48402BR	
VSN A TVI		H48402BE	
VSN A Auto IMT		H48402BT	
VSN A AMM		H48402BD	
VSN A Easy/Adv_3D		H48402BZ	
VSN A LOGIQ View		H48402BH	
VSN A DICOM		H48402BB	
VSN A CWD		H48402BC	
VSN A Needle rec		H48402BK	
VSN A B-Flow™		H48402BF	
VSN A AutoEF		H48402BS	
VSN A Follow-up Tool		H48402BN	
VSN A Thyroid productivity		H48402BY	
VSN A Tricify		H48412BB	
VSN A Auto Bladder		H48402BW	
VSN A Stress Echo		H48402BL	
VSN A BreastCare		H48402BM	
VSN A Contrast		H48402BG	
VSN A Elastography		H48402BJ	
CWD Hardware Option		H48102BM	
1T SSD		H48442BE	
isolation USB for commercial printer		H48242BC	
VSN A Base Cart		H48432BW	
Cart Paper Tray		H48442BH	
Printer and DVD Shelf		H48442BJ	
Power Cord Europe		H48482AF	
Power Cord China		H48482AK	
Power Cord India		H48482AH	
Power Cord Argentina		H48482AC	
Power Cord UK		H48482AG	
Power Cord Denmark		H48482AM	
Power Cord Switzerland		H48482AD	
Power Cord Australia		H48482AE	
Power Cord USA		H48482AL	
Power Cord Brazil		H48482AN	
Power Cord Israel		H48482AJ	
Power Cord Japan		H48482AB	

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**Versana Active – Probes and Accessories**

Probes and Accessories ^[5]	TYPE ^[6]	GEHC Cat # ^[3]
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
L8-18i-RS probe	BF	H40462LF
12S-RS probe	CF	H44901AB
9L-RS probe	BF	H40442LL
4C-RS Biopsy Kit	N/A	E8385NA
L6-12-RS Biopsy Kit	N/A	H40432LC
3Sc-RS Biopsy Kit	N/A	H46222LC
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
Biopsy Kit for 9L-RS	N/A	H4906BK
Power adapter wo cord (ACDC only)	N/A	H48442BB
VSN A Spare Battery	N/A	H48442BC

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**Versana Active – Peripherals**

Peripherals ^[5]	GEHC Cat # ^[3]
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) USA	H48492AF
BW PRINTER (UP-D898MD) EU	H48492AG
BW PRINTER (UP-D898MD) CHN	H48492AH
BW PRINTER (UP-D898MD) JPN	H48492AJ
BW PRINTER (UP-D898MD) BRA	H48492AK
898 printer paper	H41402LS
Footswitch MKF 2-MED USB GP26	H41642LS
1-Peadi type footswitch 'Whanam FSU-1000'	H41882LD
32G USB MEMORY STICK	H48442BK
1TB mobile USB HDD	H48492AB
Transcend TS8XDVDS-K DVDRW	H48442BG
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 Active – Vet Consoles and Options

Vet Consoles and Options	GEHC Cat # ^[3]
Vet probe caution label except Japan	H48492AW
Vet probe caution label	H48992LR
VSN A Vet kits	H48442BA
VSN A Vet	H48412BC

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Notes used in the tables :

- ¹ **GEHC Part #** identifies the device(s) in the manufacturer's design, manufacturing and service documentation.
- ² **REF #** is usually affixed to the device(s) in the form of a product identification or model on the rating label.
- ³ **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.
- ⁴ **Console options** are not CE marked in their own right, but covered by the CE mark of Versana Active
- ⁵ **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 Active and included relevant information to users with the Versana Active instructions for use. This activity was subject to appropriate methods of internal control and inspection.
- ⁶ **Type** identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

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