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 **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, 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

Reference of the Declaration: DOC2285658

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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 Tricefy	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-Peadl 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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