

# **DECLARATION OF CONFORMITY**

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

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, 19-Oct-2018

Gao Gan Gao Gan Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep. 30, 2018.

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\* Printed copies are uncontrolled unless otherwise identified

Before using this document, consult MyWorkshop for the lates revision

GE Healthcare Confidential



This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: DOC2177084/DOC1954045, 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
  - o harmonized standards applied on the product to which this declaration relates
    - EN 60601-1:2006 + A1:2013 Medical electrical equipment Part 1: General requirements for safety
    - EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility
    - EN 60601-1-6: 2010+ A1:2015 Medical electrical equipment Part 1-6: General requirements for safety - Collateral standard: Usability
    - EN60601-2-37:2008+A1:2015 Medical electrical equipment Part 2-37: Requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
    - EN 62366:2008 + A1:2015 Medical devices Application of usability engineering to medical devices
    - EN 62304:2006 + AC:2008 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
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: DOC2177084/DOC1954045, of the product to which this declaration relates
- For the directive 2014/53/EU (Radio Equipment Directive)
  - Technical Documentation/DHF Ref./ réf: DOC2177084/DOC1954045, of the product to which this declaration relates
  - o harmonized standards applied on the product to which this declaration relates:
    - Health & Safety (Directive 2014 2014/53/EU Art. 3(1)(a)): EN 60601-1-2: 2015; Directive 93/42/EEC; Directive 2014/30/EU; EN 60601-1: 2006/A1:2013
    - EMC (Directive 2014/53/EU Art.3(1)(b)): EN 60601-1-2: 2007 +AC: 2010 Section 6; Directive 93/42/EEC; Directive 2014/35/EU
    - Radio Spectrum (Directive 2014/53/EU Art.3(2)): EN 300 328 v 2.1.1 (2016-11); EN301 893 v 1.8.1 (2015-03) + EN 301 893 V 2.1.1 (clause 4.2.8 only)-as declared in DOC2007709.

Wuxi, 19-Oct-2018

Gao Gan Gao Gam Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep. 30 2018. ASPU

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Reference of the Declaration:



ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2177080

Versang Premier configurations— Consoels and options

Versana Premier VS         5804137         Versana Premier VS         H481528A           Versana Premier VS w flex CP         5804138         Versana Premier VS         H481528B           Versana Premier VA         5804136         Versana Premier VA         H48152BC           Versana Premier VA w 4D         5804139         Versana Premier VA         H48152BC           Versana Premier VA         H48152BC         Wssana Premier VA         H48152BC           Versana Premier VA         H48152BC         Wssana Premier VA         H48152BC           VSN Premier DICOM         H48162BA         Wssana Premier VA         H48162BA           VSN Premier Follow up tool         H48162BB         Wssana Premier Collow         H48162BB           VSN Premier LOGIQ VIEW         H48162BB         Wssana Premier Collow         H48162BB         Wssana Premier Collow         H48162BB         Wssana Premier Collow         Wssana Premier Collow         H48162BB         Wssana Premier Collow         H48162BC         Wssana Premier Collow         H48162BC         H48162BC         Wssana Premier			s– Consoels and opt	ions
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Versana Premier VA         5804136         Versana Premier VA         H48152BC           Versana Premier VA w 4D         5804139         Versana Premier VA         H48152BE           Options Consoles         GEHC Cat # <sup>[5]</sup> WN Premier DICOM         H48162BA           VSN Premier DICOM         H48162BB         WN Premier Brollow up tool         H48162BB           VSN Premier Follow up tool         H48162BC         WN Premier Brollow up tool         WN Premier Brollow up tool           VSN Premier LOGIQ VIEW         H48162BD         WN Premier Brollow up tool         H48162BD           VSN Premier Easy/Adv 3D         H48162BD         WN Premier Controst         H48162BE           VSN Premier Contrast         H48162BE         WN Premier Tricefy Uplink         H48162BE           VSN Premier Topink         H48162BF         WN Premier VOCAL         H48162BH           VSN Premier VOCAL         H48162BH         WN Premier Triving Premier Stress Echo         H48162BK           VSN Premier AMM         H48162BN         WN Premier AMM         H48162BN           VSN Premier Redele rec         H48162BR         WN Premier Redele rec         H48162BR           VSN Premier Breast Care         H48162BS         WN Premier Thyroid prod         H48162BC           VSN Premier Thyroid prod         H48162BC		5804137	Versana Premier VS	H48152BA
Versana Premier VA w 4D  S804139  Versana Premier VA  H48152BE  Options Consoles  GEHC Cat # <sup>[5]</sup> VSN Premier DICOM  H48162BA  VSN Premier Follow up tool  VSN Premier Follow UFW  H48162BB  VSN Premier Easy/Adv 3D  VSN Premier B-flow/color  VSN Premier Tricefy Uplink  VSN Premier Tricefy Uplink  VSN Premier 4D software  VSN Premier Auto IMT  VSN Premier Auto IMT  VSN Premier AWN  VSN Premier AWN  VSN Premier Stress Echo  H48162BN  VSN Premier AWN  VSN Premier WORAL  VSN Premier AWN  VSN Premier Breast Care  VSN Premier Redle rec  VSN Premier Breast Care  VSN Premier Thyroid prod  H48162BZ  VSN Premier Thyroid prod  H48162BZ  VSN Premier Thyroid prod  H48162BA  VSN Premier Breast Care  H48162BA  VSN Premier Breast Care  H48162BA  VSN Premier Gel Warmer  H48162BA  VSN Premier H48162BBA  VSN Premier H48162BBA		5804138	Versana Premier VS	H48152BB
Options Consoles  GEHC Cat # (5)  VSN Premier DICOM  H48162BA  VSN Premier Follow up tool  H48162BB  VSN Premier LOGIQ VIEW  H48162BC  VSN Premier B-flow/color  VSN Premier Follow up tool  H48162BE  VSN Premier Contrast  H48162BE  VSN Premier Tricefy Uplink  H48162BF  VSN Premier Tricefy Uplink  H48162BH  VSN Premier VOCAL  H48162BJ  VSN Premier Auto IMT  H48162BL  VSN Premier AWM  H48162BL  VSN Premier Stress Echo  H48162BN  VSN Premier Auto EF  VSN Premier Auto EF  VSN Premier CODD  H48162BR  VSN Premier Needle rec  H48162BS  VSN Premier Breast Care  H48162BV  VSN Premier Breast Care  H48162BV  VSN Premier Thyroid prod  H48162BC  VSN Premier Thyroid prod  H48162BC  VSN Premier Thyroid prod  H48162BC  VSN Premier Othor  H48162BC  VSN Premier Gel Warmer  isolation USB for AC printer  H48192BM  VSN P Battery Install Kit  H48182BD  VSN Premier Articular Arm  H48182BJ		5804136	Versana Premier VA	H48152BC
VSN Premier DICOM  WH48162BA  VSN Premier Follow up tool  WSN Premier Easy/Adv 3D  WSN Premier Easy/Adv 3D  WSN Premier Enfow/color  WSN Premier Follow Uplink  WSN Premier Follow Uplink  WSN Premier Tricefy Uplink  WSN Premier VOCAL  WSN Premier Auto IMT  WSN Premier Auto IMT  WSN Premier Stress Echo  WSN Premier Stress Echo  WSN Premier Auto EF  WSN Premier Auto EF  WSN Premier WOCAL  WSN Premier Auto EF  WSN Premier Breast Care  WSN Premier Needle rec  H48162BS  WSN Premier Breast Care  H48162BT  WSN Premier Thyroid prod  H48162BZ  WSN Premier Gel Warmer  isolation USB for AC printer  Battery  Battery  WSN Premier APP HW option  H48182BJ  WSN Premier AFP HW 18482BJ  WSN Premier AFP HW option  H48182BJ		5804139	Versana Premier VA	H48152BE
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VSN Premier Articular Arm H48182BJ				
	paper tray		H48182BF	

### Notes used in the table :

- 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.
- 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.

Wuxi, 19-Oct-2018

Gao Gan Gao Gan

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Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated sep.30, 2018

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Reference of the period tion: DOC

1 199

10 (Rev. 02)



### Versana Premier - Probes with Accessories

PROBES and Accessories [4]	TYPE [5]	GEHC Cat # [3]
4C-RS Convex array probe	BF	H4000SR
E8C-RS probe	BF	H40402LN
8C-RS Convex array probe	BF	H40402LS
L8-18i-RS	BF	H40462LF
BE9Cs-RS	BF	H40482LN
6S-RS	BF	H45021RP
3Sc-RS Phased Array probe	BF	H45041DL
L6-12-RS Linear Array probe	BF	H48062AC
E8Cs-RS	BF	H48062AF
RAB2-6-RS probe	BF	H48681WR
12L-RS	BF	H40402LY
12S-RS	BF	H44901AB
LK760-RS	BF	H44901AF
RIC5-9A-RS	BF	H48701EJ
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
BE9CS disposal	N/A	E8387M
BE9CS Reusable	N/A	E8387MA
12L Transverse bracket	N/A	H48392LL
Infinite 12L biopsy kit	N/A	H48392LT
Reusable Biopsy Guide for RIC5-9A-RS	N/A	H46721R
Disposable Biopsy Guide for RIC5-9A-RS	N/A	H48681GF
Disposable Biopsy Guide with Covers for RIC5-9A-RS	N/A	H48691Z

#### Notes used in the table:

 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. Probes and accessories 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 Premier and included relevant information to users with the Versana Premier instructions for use. This activity was subject to appropriate methods of internal control and inspection.

5. Type identifies the degree of protection against electric shock for each probe, as labeled on the probe itself.

Wuxi, 19-Oct-2018

Gao Gan Gao Gam Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep. 30, 2018

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Reference of the Decidration

Decidration: DOC2177080 [Rev. 02]



### Versana Premier – Accessories

Accessories [6]	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)	H48492AZ
UP-D898DC Printer	H48052BG
Versana Premier printer shelf	H48192BF
898 printer paper	H41402LS
UP-D898MD DC Printer OFC	H48192BN
Footswitch MKF 2-MED USB GP26	H41642LS
1-Peadl type footswitch 'Whanam FSU-1000'	H41882LD
USB Stick	H48962LC
1TB mobile USB HDD	H48492AB
Transcend TS8XDVDS-K DVDRW kit with SW	H48192BL
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
Bluetooth Adaptor	H48122BT
SonoStore White Label	H48902AJ
SonoStore Blue Label	H48902AH
EMI Filter	H48242BD

### Notes used in the table:

- 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.
- 6. Accessories 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 Premier and included relevant information to users with the Versana Premier instructions for use. This activity was subject to appropriate methods of internal control and inspection.

Wuxi, 19-Oct-2018

Gao Gan Gao Gana Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated \$6010,2018

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Reference of the Declaration: DOC2177080 (Rev. 02)



## Versana Premier – Vet Consoles and Options

Vet Consoles and Options	GEHC Cat # [3]
VSN Premier VS vet console	H48152BG
VSN Premier VS w flex CP vet console	H48152BH
VSN Premier VA vet console	H48152BJ
Vet probe caution label	H48492AW
Vet probe caution label	H48992LR
Versana Premier Vet kits	H48182BE

### Notes used in the table:

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.

Wuxi, 19-Oct-2018

Gao Gan *Gao Gam* Regulatory Affairs

This EC declaration of conformity for Versana Premier, replaces the previous dated Sep.30, 2018.

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Reference of the Declaration: