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
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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.

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
  - 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
  - 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

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ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2177080
Versana Premier configurations– Consoels and options

CONSOLE Name with description	GEHC Part [1]	REF # [2]	GEHC Cat # [3]
Versana Premier VS	5804137	Versana Premier VS	H48152BA
Versana Premier VS w flex CP	5804138	Versana Premier VS	H48152BB
Versana Premier VA	5804136	Versana Premier VA	H48152BC
Versana Premier VA w 4D	5804139	Versana Premier VA	H48152BE
Options Consoles	**GEHC Cat # [3]**		
VSN Premier DICOM	H48162BA		
VSN Premier Follow up tool	H48162BB		
VSN Premier LOGIQ VIEW	H48162BC		
VSN Premier Easy/Adv 3D	H48162BD		
VSN Premier B-flow/color	H48162BE		
VSN Premier Contrast	H48162BF		
VSN Premier Tricefy Uplink	H48162BG		
VSN Premier 4D software	H48162BH		
VSN Premier VOCAL	H48162BJ		
VSN Premier Auto IMT	H48162BK		
VSN Premier TVI	H48162BL		
VSN Premier AMM	H48162BM		
VSN Premier Stress Echo	H48162BN		
VSN Premier Auto EF	H48162BP		
VSN Premier CWD	H48162BR		
VSN Premier Needle rec	H48162BS		
VSN Premier Elastography	H48162BT		
VSN Premier Breast Care	H48162BW		
VSN Premier Thyroid prod	H48162BZ		
VSN Premier VA-IQ	H48172BA		
4D Hardware option	H48172BW		
VSN Premier Gel Warmer	H48182BA		
isolation USB for AC printer	H48242BC		
Battery	H48772AT		
Battery kit	H48192BM		
VSN P Battery Install Kit	H48182BD		
VSN Premier 4PP HW option	H48182BH		
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.
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

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

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 :

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. **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

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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

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

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

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