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.

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

Gao Gan Gao Gan
Regulatory Affairs

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

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

Gao Gan Gao Gan
Regulatory Affairs

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

Gao Gan Gao Gan
Regulatory Affairs

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

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-Pedal 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 Gan
Regulatory Affairs

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

Gao Gan Gao Gan
Regulatory Affairs

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

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60116081 0001

Report No.: 15094929 004

Manufacturer:

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

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60110059 0001

Expiry Date: 2021-05-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-01-03

Date: 2017-01-03

Notified Body TÜV Rheinland LGA Products GmbH
X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60116081 0001
Report No.: 15094929 004

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

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Storage of Ultrasound Diagnostic Systems

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2017-01-03

TÜVRheinland®

Doc. 1/1, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60116081 0001
Report No.: 15094929 005

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

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech
Development Zone, Jiangsu 214028, P.R.China

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

Date: 2017-12-20

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

**Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-12-20
Certificate Registration No.:	SX 60123505 0001
An audit was performed. Report No.:	15094484 005
This Certificate is valid until:	2020-06-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-12-20

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60123505 0001
Report No.: 15094484 005

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

Scope:

Products:
- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:
GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture and Distribution of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.
No.22, Gao Lang East Road, Wuxi National Hi-Tech Development Zone, Jiangsu 214028, P.R.China

Storage and Distribution of Ultrasound Diagnostic Systems and Probes, Anesthesia Devices, Bone Densitometry Systems, ECG Module

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

S. Liu

Date: 2017-12-20

Societatea cu Raspundere Limitata
"Intermed"

Republica Moldova,
mun. Chişinău, str. Tighina 65
tel: (373-22) 54-91-20
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BC "Moldova Agroindbank" SA
sucursala M. Eminescu
Cod fiscal/TVA 1002600034804/0206649
Cod IBAN MD06AG000002251748012675

ALL CERT
Nr. Certificate: 03299
ISO 9001: 2015

In atentia Aparatul presedintelui raionului Straseni

DECLARATIE OFERTANT

Prin prezenta, compania "Intermed"SRL care participa in licitatia publica nr. ocds-b3wdp1-MD-1554367201735 privind procurarea aparatului UZI – ecograf multidisciplinar pentru IMSP CS Straseni, declara/confirma:

1. Termenul de garantie pentru echipament nu mai mic de 36 luni din data instalarii.
2. Timp de raspuns la solicitare in perioada de garantie cel mult 48 ore la sediul beneficiatului/locatia de instalare.
3. Asistenta de aplicatii pe perioada de garantie – gratuit.
4. Instruirea personalului medical si ethnic care va opera echipamentul la sediul beneficiarului/locul de functionarese va face gratuity prin grija furnizorului.
5. Timp de raspuns la solicitare in perioada de post-garantie cel mult 48ore la sediul beneficiarului.
6. Transportarea, instalarea, punerea in functiune se realizeaza de personalul specializat instruit de producator nu implica costuri suplimentare pentru beneficiar, fiind incluse déjà in oferta.
7. Manualele de operare in limba engleza si romana vor fi livrate impreuna cu echipamentul.
8. Termen de livrare: 30zile.

Director "Intermed"SRL
A.Ceaicovschi