



EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745

Following the directive 2011/65/EU, directive 2014/53/EU

We:

Manufacturer	EU Authorized Representative
GE Medical Systems (China) Co., Ltd. No. 19, Changjiang Road WuXi National Hi-Tech Dev. Zone 214028 Jiangsu, China Single Registration Number (SRN): CN-MF-000001856	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France SRN: SRN: FR-AR-000000344
Manufacturer Site	Manufacturer Site
GE Medical Systems (China) Co., Ltd. No. 19, Changjiang Road WuXi National Hi-Tech Dev. Zone 214028 Jiangsu, China	Wipro GE Healthcare Private Ltd. No. 4, Kadugodi Industrial Area, BANGALORE 560 067, KARNATAKA, INDIA

Declare under our sole responsibility that the device:

Versana Essential

Basic UDI-DI: 8406821BUG00287HU

Version: R2

Identification number/REF:

REF #	Part number	UDI-DI
Versana Essential R2 VA	5887882	00195278503411
Versana Essential R2 VS	5887857	00195278503404
Versana Essential R2 VS India	5919590	00195278556479
Versana Essential R2 VA India	5919591	00195278556462

Intended Purpose: The Versana Essential is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.

Date of issue: 20-March-2023

Name: Xie Jian *Xie Jian*

Place of issue: China Wuxi

Function: Regulatory Affairs Leader

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GMDN Code: 40761
GMDN Description: General-purpose ultrasound imaging system
EMDN Code: Z110401
EMDN Description: Ultrasound scanners
Class: IIa
Classification rule (Annex VIII): Rule 10, Class: IIa

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that 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 (RoHS) and the directive 2014/53/EU on the radio equipment (RED).

This conformity is based on the following elements:

- Technical Documentation reference: DOC2757252, of the product to which this declaration relates.
- EC certificate HZ2096373-1
Conformity assessment procedure followed: Annex IX of the medical device regulation 2017/745
Delivered by TÜV Rheinland LGA Products GmbH (0197)

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ADDENDUM to THE DECLARATION OF CONFORMITY
Versana Essential configurations – Accessories and Components/Options

Note: This ADDENDUM can only be used together with the EU DECLARATION OF CONFORMITY dated on 10-February -2023.

Device Name / with description	GE Part / REF # ^[1]	GEHC Cat # ^[2]
Versana Essential/Versana Essential R2 VA	5887882 /Versana Essential R2 VA	H48902CB
Versana Essential/Versana Essential R2 VS	5887857 /Versana Essential R2 VS	H48902CA
Versana Essential/Versana Essential R2 VA w CWD	5887882 /Versana Essential R2 VA	H48902CC
Versana Essential/Versana Essential R2 VS IND	5919590/Versana Essential R2 VS India	H48902CD
Versana Essential/Versana Essential R2 VA IND	5919591/Versana Esstnal R2 VA India	H48902CE
Versana Essential/Versana Essential R2 VA w CWD IND	5919591/Versana Esstnal R2 VA India	H48902CF
Software options	GEHC Cat # ^[2]	
Versana Essential R2 Scan Coach	H48922CD	
Versana Essential R2 SonoBiometry	H48922CE	
Versana Essential R2 TVI	H48912CD	
Versana Essential R2 Auto IMT	H48912CP	
Versana Essential R2 AMM	H48912CC	
Versana Essential R2 Easy/Adv_3D	H48912CS	
Versana Essential R2 LOGIQ View	H48912CG	
Versana Essential R2 CWD	H48912CB	
Versana Essential R2 Needle rec	H48912CJ	
Versana Essential R2 B-Flow™	H48912CE	
Versana Essential R2 AutoEF	H48912CN	
Versana Essential R2 Follow-up Tool	H48912CM	
Versana Essential R2 Thyroid productivity	H48912CR	
Versana Essential R2 Tricfy Uplink	H48912CY	
Versana Essential R2 Auto Bladder	H48922CA	
Versana Essential R2 Stress Echo	H48912CK	
Versana Essential R2 BreastCare	H48912CL	
Versana Essential R2 V-Live 4D	H48912CT	
Versana Essential R2 Elastography	H48912CH	
Versana Essential R2 VOCAL	H48912CW	
Versana Essential R2 Contrast	H48912CF	
Versana Essential R2 LI-RADS®	H48922CC	

Notes used in the table :

1. **GE Part / REF #** is usually affixed to the device(s) in the form of a product identification or model on the rating label.
2. **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.

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Hardware options	GEHC Cat # [2]
Versana Essential R2 4D Hardware	H48172BW
Versana Essential R2 4D Hardware and Software Package	H48982CR
Versana Essential R2 Battery charger	H48902CH
Versana Essential R2 Spare Battery	H48442BC
Versana Essential R2 Battery Kit	H48982CN
Versana Essential R2 Rear Handle Kit	H48902CL
Versana Essential R2 898DC Printer shelf kits	H48982CS
Versana Essential R2 898MD Printer shelf kits	H48982CT
Power box external grounding cable	H48342BS
Isolation USB for AC printer	H48242BC
Versana Essential R2 probe holder for GYN probe	H48182BG
Versana Essential R2 Internal Extended 256GB SSD	H48902CJ
Versana Essential R2 CWD Hardware Option	H48102BM
Versana Essential R2 CWD Package	H48982CP
Versana Essential R2 Foot Rest Kit	H48902CK
Other options	GEHC Cat # [2]
AN Keyboard film Russian	H48182BL
AN Keyboard film French	H48182BR
AN Keyboard film German	H48182BS
AN Keyboard film Greek	H48122BC
Russian language A N keyboard film	H48122BB
Versana AN Keyboard film Swedish/Finnish	H48122BD
Versana AN Keyboard film Norwegian	H48122BE
Versana AN keyboard protective film	H48122BG
Versana Essential Control Panel protective film	H48902BD
Versana Essential R2 Chinese KBD film	H48902CN
Versana Essential V2 SW e-Delivery	H48052DDED
Versana Essential V2 SW Release Kit	H48042DT

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**Versana Essential – Probes with Accessories**

PROBES and Accessories [3]	GEHC Cat # [2]
4C-RS Convex array probe	H4000SR
E8C-RS probe	H40402LN
8C-RS Convex array probe	H40402LS
6S-RS Phased Array probe	H45021RP
3Sc-RS Phased Array probe	H45041DL
L6-12-RS Linear Array probe	H48062AC
E8Cs-RS	H48062AF
RAB2-6-RS probe	H48681WR
LK760-RS	H44901AF
4C-RS Biopsy Kit	E8385NA
L6-12-RS Biopsy Kit	H40432LC
3Sc-RS Biopsy Kit	H46222LC
RAB2-6-RS Biopsy Kit	H48681ML
E8C-RS Biopsy Kit	E8385MJ
E8C-RS Reusable Biopsy Kit	H40412LN
BE9CS disposal	E8387M
BE9CS Reusable	E8387MA

Notes used in the table :

2. **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.
3. 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 Essential, and included relevant information to users with the Versana Essential instructions for use. This activity was subject to appropriate methods of internal control and inspection.

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**Versana Essential – Peripherals and Accessories**

Peripherals and Accessories ^[3]	GEHC Cat # ^[2]
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
SONY UPD25 Color Printer kit	H48532AM
Versana Essential R2 Printer starter Kit for 898MD	H48982CY
Versana Essential R2 Printer starter Kit for 898DC	H48982CM
898 printer paper	H41402LS
UP-D898MD DC Printer OFC	H48192BN
USB 3.0 Stick	H48532BH
1TB mobile USB HDD	H48492AB
Transcend TS8XDVDS-K DVDRW	H48312BJ
ECG ASSY With AHA CABLE	H48392BN
ECG ASSY With IEC CABLE	H48392BP
ECG ASSY for Germany	H48392BR
wireless Adaptor	H48832AC
Bluetooth Adaptor	H48122BT
Versana Essential R2 Barcode reader	H48542AE
Video Output Adapter	H48722BE
EMI Filter	H48242BD
Footswitch MKF 2-MED USB GP26	H41642LS
1-Peadl type footswitch 'Whanam FSU-1000'	H41882LD

Notes used in the table :

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