



## Declaration of Conformity

### DECLARATION OF CONFORMITY

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

We

Manufacturer  
**GE HEALTHCARE (TIANJIN) COMPANY LIMITED**  
**No.266 JINGSAN ROAD**  
**TIANJIN AIRPORT ECONOMIC AREA**  
**TIANJIN, P.R. CHINA 300308**

EU Authorized Representative  
**GE Medical Systems SCS**  
**283 rue de la Minière**  
**78530 BUC, France**

Manufacturing  
**GE HEALTHCARE (TIANJIN) COMPANY LIMITED**  
**No.266 JINGSAN ROAD**  
**TIANJIN AIRPORT ECONOMIC AREA**  
**TIANJIN, P.R. CHINA 300308**

**GE Healthcare Manufacturing LLC**  
**3001 West Radio Drive**  
**Florence, SC 29501, USA**

Declare under our sole responsibility that the device:

**SIGNA Creator, SIGNA Explorer (Software SV25.3)**

Ref: see addendum

GMDN Code: **37654** UDI-DI code: **840682113786, 8406821**

Classification rule (93/42/EEC Annex IX): **Rule 10**, Class IIa



**PHAM HONG SON**  
**General Director**  
**Tổng Giám Đốc**

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.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: **DOC1855025** of the product to which this declaration relates
  - EC certificate: approval of production quality assurance (Annex V of the directive 93/42 EEC) delivered by G-med (0459) / Certificate N Certificate N° 27771
  - harmonized standards applied on the product to which this declaration relates / réf: see Addendum
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: **DOC1892615, DOC2160883, DOC2179593, DOC2306895** of the product to which this declaration relates

Tianjin,  
July 22, 2020

*James McMahon*  
James McMahon  
Senior Regulatory Affairs Director – MR

**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1894761****SIGNA Creator and SIGNA Explorer – Unique Components by Configuration Category**

<b>Configuration Category</b>	<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
Main config only	M5000AS	1.5T LCC MAG W NEW ENCL	Optional	Optional
	M50012FG	16 Beat Magnet in Tianjin	Optional	Optional
	M5001AS	1.5T Mulan W Magnet-FLO made	Optional	Optional
	M50022CG	1.5T Mulan W Magnet-TJ made	Optional	Optional
Bloom Only	M50022BF (G5000AC, G5000AD, G5000AE)	Explorer Upgrade Kit Collector	Mandatory	Mandatory
	M50022BD	Explorer Upgrade Kit Collector – Tianjin	Mandatory	Mandatory
	M50022BC	Short RF Body Coil	Mandatory	Mandatory
	M50022BB	BRM Gradient Coil Upgrade Collector	Optional	Optional
Delta Only	M50022AZ (G50022CD)	Mulan Delta Base Electronic	No	Mandatory
	M50023AZ	Mulan Delta Base Electronic	No	Mandatory
	M50022AK	16ch LPCA	No	Optional
	M50022AL	16ch Magnet side kit	No	Optional
	M50022AM	Enclosure Accessories	No	Optional

**SIGNA Creator and SIGNA Explorer Common Components and accessories**

<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
M50022LN	Explorer Enclosures	No	Mandatory
M50012LN	Creator Enclosures	Mandatory	No
M50002NS	Display Panel	Mandatory	Mandatory
M50002LT	16Beat Long Cable	Optional	Optional
M50002LW	16Beat Short Cable	Optional	Optional
M50002HY	MR TOUCH ACC KIT - OPTIMA	No	Optional
M7000MT	MR TOUCH	No	Optional
M7100MT	MR TOUCH-Application only	No	Optional
M3088TM	TWSP/HDE MAIN DISC PANEL	Optional	Optional
M1060SR	2.5M CEILING HT KIT	Optional	Optional
M1060KM	MR ROOM OXYGEN MONITOR	Optional	Optional
M1000MW	WIDE OPERATOR TABLE MONITOR	Optional	Optional
M50002DF	RF CBL EXTENSION KIT 5M	Optional	Optional
M50002LP	SV VIBROACOUSTIC KIT-MAG	Mandatory	Mandatory
E8802F	TMJ POSITIONING DEVICE	Optional	Optional
E8811ED	Adult Bellows Assembly for MRI Respiratory Cardiac Gating	Optional	Optional



<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
E8811EJ	SMALL PERSON BELLOWS FOR MRI	Optional	Optional
E8819HZ	ECG Patient Lead Wire for Vector Gating	Optional	Optional
E88241A	SYSTECH_EC96_O2_MONITOR	Optional	Optional
M50012AN	Standard Table	No	Optional
M3335CB	1.5T CALIBRATION PHANTOMS	Optional	Optional
M3335CA	PHANTOM CART	Optional	Optional
M3335EW	1.5T UNIFIED PHANTOM KIT	Optional	Optional
M50002HD	8ch Rear Pedestal	Mandatory	No
M50002HE	16ch Rear Pedestal	Optional	Mandatory
M50012HG	Explorer Software Identifier	No	Mandatory
M50012HF	Creator Software Identifier	Mandatory	No
M5000AF	6kW Lytron MCS	Optional	Optional
M5000AG	8KW LYTRON LCS	Optional	Optional
M5000AH	4KW LYTRON LCS BRM	Optional	Optional
M1085KA	4KW GRADIENT CHILLER	Optional	Optional
M50002BH	11KW AISYS CHILLER 50HZ	Optional	Optional
M50002BJ	11KW AISYS CHILLER 60HZ	Optional	Optional
M1060JW	COLD HEAD COMPRESSOR	Optional	Optional
M50002BK	LCC F50-L COMP 10M P-CBL	Optional	Optional
M29762SS	SUMITOMO COMPRESSOR air-cooled 200V	Optional	Optional
M3335SJ	COOLANT - 3 GALLONS	Optional	Optional
M50002BL	MCS ACC KIT /PIUMBING	Optional	Optional
M50002BM	MCS ACC KIT	Optional	Optional
M50002BN	LCS ACC KIT	Optional	Optional
M50002BP	FACILITY WATER ACC KIT	Optional	Optional
M20152FE	OUTDOOR EXT FLECKLINE 20M	Optional	Optional
M3033MW	iDRIVE Pro Plus	Optional	Optional
M7000CF	MDE and BBSSFSE	Optional	Optional
M3333WG	Probe-P single voxel PRESS	Optional	Optional
M3333WJ	Probe-2D CSI	Optional	Optional
M3340AJ	Inhance	Optional	Optional
M3033MH	TRICKS	Optional	Optional
M3090LR	DTI	Optional	Optional
M3033NK	TRACTOGRAPHY	Optional	Optional
M7000CK	QuickStep	Optional	Optional
M3340AG	SWAN	Optional	Optional
M3340AC	IDEAL	Optional	Optional
M7000CP	IDEAL	Optional	Optional
M7000PF	MAVRIC SL	Optional	Optional
M7000CC	PROSE	No	Optional
M3335KY	T2 MAPPING	Optional	Optional
M3033ND	VIBRANT-II	Optional	Optional
M3335KK	BREAST SPECTROSCOPY	Optional	Optional
M3033MF	3D FATSAT FIESTA CARDIAC	Optional	Optional



<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
M3033MY	CARDIAC TAGGING FOR EXCITE	Optional	Optional
M7001SL	3D PROMO T2 and T2 FLAIR	No	Optional
M7001SA	1.5T Silent GEM Pkg FP	No	Optional
M7001SE	FOCUS	Optional	Optional
M7001SF	Body Navigators	No	Optional
M3033MD	3D DELAYED ENHANCEMENT	Optional	Optional
M3340AE	StarMap Acquisition	Optional	Optional
M7000JA	Propeller 3.0	Optional	Optional
M3340BB	INHANCE DELTA FLOW 16.0	Optional	Optional
M3340AP	LAVA-Flex	Optional	Optional
M3340AW	FGRE-Time Course	Optional	Optional
M3340AY	3D Heart	No	Optional
M3340BA	3D ASL	Optional	Optional
M3340AR	eDWI	Optional	Optional
M7000PG	IDEAL IQ	Optional	Optional
M3333WK	Probe-3D CSI	Optional	Optional
M50002HT	SWAN 2.0	Optional	Optional
M50002HW	Express Spine Annotation	Optional	Optional
M3340AT	CINE-IR	Optional	Optional
M7006AZ	ESI	Optional	Optional
M7006AH	SIGNASecure Advanced	NA	Optional
M1087EE	POSITIONER HEAD HOLDER	Optional	Optional
M3335MG	1.5T HD DUAL ARRAY ADAPT	Optional	Optional
M50002MA	BULGARIA LANGUAGE KIT	Optional	Optional
M50002MC	CROATIAN LANGUAGE KIT	Optional	Optional
M50002MD	CZECH LANGUAGE KIT	Optional	Optional
M50002ME	DANISH LANGUAGE KIT	Optional	Optional
M50002MF	DUTCH LANGUAGE KIT	Optional	Optional
M50002MG	ENGLISH LANGUAGE KIT	Optional	Optional
M50002MH	ESTONIAN LANGUAGE KIT	Optional	Optional
M50002MJ	FINISH Multi-Language Kit	Optional	Optional
M50002MK	FRENCH LANGUAGE KIT	Optional	Optional
M50002ML	GERMAN LANGUAGE KIT	Optional	Optional
M50002MM	GREEK LANGUAGE KIT	Optional	Optional
M50002MN	HUNGARIAN LANGUAGE KIT	Optional	Optional
M50002MP	ITALIAN LANGUAGE KIT	Optional	Optional
M50002MT	LATVIAN LANGUAGE KIT	Optional	Optional
M50002MW	LITHUANIAN LANGUAGE KIT	Optional	Optional
M50002MY	NORWEGIAN LANGUAGE KIT	Optional	Optional
M50002MZ	POLISH LANGUAGE KIT	Optional	Optional
M50002NA	PORTUGUESE LANGUAGE KIT	Optional	Optional
M50002NB	ROMANIAN LANGUAGE KIT	Optional	Optional
M50002ND	SERBIA LANGUAGE KIT	Optional	Optional
M50002NE	SLOVAKIAN LANGUAGE KIT	Optional	Optional



<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
M50002NF	SPANISH LANGUAGE KIT	Optional	Optional
M50002NG	SWEDISH LANGUAGE KIT	Optional	Optional
M50002NH	TURKISH LANGUAGE KIT	Optional	Optional
M5002AC	New Color DOCK COLLECTOR	No	Optional
M5002AE	New Color PATIENT TBL - LITE	No	Optional
M50002LL	Lower Height Fixed Table	Optional	Optional
M50012LL	Lower Height Fixed Table (200kg)	Optional	Optional
M50022LL	Lower Height Fixed Table-India	Optional	Optional
M50002DG	STANDARD TBL PAD KIT	Mandatory	Mandatory
M50002DH	LITE TBL PAD KIT	No	Optional
M3340GS	1.5T Magnet Crate Enhanced	Optional	Optional
M3340GM	1.5T Magnet Crate Standard	Optional	Optional
M3340GP	1.5T Magnet Crate 96 inch	Optional	Optional
M1060KN	Remote Magnet Rundown Unit	Optional	Optional
M3340BZ	NBR COMPLIANT POWER CABLE	Optional	Optional
M3335TZ	STEPPDOWN TRANSFORMER	Optional	Optional
M50012AP	Mulan Collector Kit	Mandatory	Mandatory
M50012HD	8ch Rear Pedestal	Mandatory	No
M70012SD	APX	Optional	Optional
M7005DH	Magic 1.5T	No	Optional
M70012SJ	CUBE DIR	Optional	Optional
M7006AC	Cardiac T1/T2 mapping	NA	Optional
M7005DB	DISCO	NA	Optional
M50022AE	Signa Creator Explorer Plus Collector Kit	Mandatory	Mandatory
M50022SL	Signa Creator Explorer LONG Scan Room Kit	Optional	Optional
M50022SS	Signa Creator Explorer Short Scan Room Kit	Optional	Optional
M50032SL	Signa Creator Explorer LONG Scan Room Kit	Optional	Optional
M50032SS	Signa Creator Explorer Short Scan Room Kit	Optional	Optional
M50022SE	Signa Creator Explorer Equipment Room Cable Collector	Optional	Optional
M50022CA	ECG, Photo-plethysmograph and Patient comfort hose kit	Optional	Optional
M50032SE	Signa Creator Explorer Equipment Room Cable Collector	Optional	Optional
M50022CE	ECG, Photo-plethysmograph and Patient comfort hose kit	Optional	Optional
M50022CC	Gradient cables and Ground cables kit - Long	Optional	Optional
M50022CD	Gradient cables and Ground cables kit - Short	Optional	Optional
M7006LK	GEM Flex Knee Stabilization positioner for Curved table	No	Optional
M7006LM	GEM Flex Stabilization Pad and General Purpose Strap	No	Optional
M50012AE	Creator Plus Base Electronics	Mandatory	No
M50012AF	Explorer Plus Base Electronics	No	Mandatory
M50022AC	SIGNA Creator Plus Base Electronics-China	Optional	No



Mcat Number	Description	SIGNA Creator	SIGNA Explorer
M50022AA	SIGNA Explorer Plus Base Electronics-China	No	Optional
M50022AF	SIGNA Explorer Plus Base Electronics-US	No	Optional
M50022AG	SIGNA Creator Plus Base Electronics-US	Optional	No
M50022AS	SIGNA Explorer Plus Base Electronics-India	No	Optional
M50022AR	SIGNA Creator Plus Base Electronics-India	Optional	No
M50022MA	Main Disconnect Panel	Optional	Optional
R34023AC	Standard Service Package	Optional	Optional
M7000EZ	Flow Analysis 4.0 on Console	Optional	Optional
M50022DB	Explorer Magnet Enclosure - China Made	NA	Optional
M50022DA	Creator Magnet Enclosure - China Made	Optional	NA
M50022DE	Explorer Trim ring	NA	Optional
M50022AP	SV25.2 Software upgrade kit	Optional	Optional
M7006AF	HyperSense	Optional	Optional
M7006AG	HyperCube	Optional	Optional
M7006AE	MAGiC DWI	Optional	Optional
M7006AW	Flex for FSE Cube	Optional	Optional
M7006AB	ViosWorks 4D	NO	Optional
M7006AD	ViosWorks 3D 4D	NO	Optional
M7006AM	ViosWorks 3D	NA	Optional
M7006BD	ViosWorks Flex Trial up to 30	NO	Optional
M7006BM	ViosWorks PHI Service Hardware	NO	Optional
M7006BS	ViosWorks Cloud Analysis 1 year	NO	Optional
M7006BH	CMR42 stand-alone 1 user	NO	Optional
M7006BJ	CMR42 stand-alone 3 concurrent users	NO	Optional
M7005DA	MDE PLUS	NA	Optional
M70072AM	LX DWI PROPELLER	Optional	Optional
M70072AN	CUBE STIR	Optional	Optional
M70072AP	WB DWI	Optional	Optional
M50022AN	XFD PS	Optional	Optional
M50012HE	16-channel Rear Pedestal	Optional	Optional
M50022AE	Signa Creator Explorer Plus Collector Kit	Mandatory	Mandatory
M3335MT	LCD Monitor	No	Optional
G50022CN	Front Trim Ring Assembly for Explorer (led light)	NO	Optional
G3335JZ	1.5T HDX SPHEAD COIL collector	Optional	Optional
G3335LJ	1.5T HDX COIL ADAPT1CH	Optional	Optional
M50023AC	Signa Creator Plus Base Electronics Skylake-China	Mandatory	NA
M50023AA	Signa Explorer Plus Base Electronics Skylake-China	NA	Mandatory
M50023AG including G50022AC, G50022AD, G50022AL, G50023AM, G50023BJ;	Signa Creator Plus Base Electronics Skylake -US	Mandatory	NA



<b>Mcat Number</b>	<b>Description</b>	<b>SIGNA Creator</b>	<b>SIGNA Explorer</b>
M50023AF including G50022AC, G50022AD, G50022AL, G50023AM, G50023BK;	Signa Explorer Plus Base Electronics Skylake-US	NA	Mandatory
M50023AR	Creator Plus Base Electronics Skylake - India	Mandatory	NA
M50023AS	Explorer Plus Base Electronics Skylake - India	NA	Mandatory
M50023AQ	Power cable and Audio cable kit	Optional	Optional
M50023AX	Upgrade config from Creator (Skylake) to Explorer (Skylake)	NA	Optional
M50023AP	SW upgrade kit from SIGNA Creator/Explorer Mulan Plus (25.1/2) to Skylake (25.3)	Optional	Optional
M50023AY	Upgrade kit from SIGNA Creator/Explorer Mulan Plus (25.1/2) to Skylake (25.3)	Optional	Optional
M70012RJ	Sand bag	Optional	Optional
M50023AT	Skylake upgrade kit for Signa Creator/Explorer from Mulan to Mulan Skylake	Optional	Optional



---

**List of harmonized standards applied for CE marking**

EN 60601-1:2006 +A12:2014
EN60601-1-2:2015
EN60601-1-6:2010 +A1:2015
EN 60601-2-33:2010 +A12:2016
EN62304:2006 +A1:2015
EN62366-1:2015
EN ISO 15223-1: 2016
EN ISO10993-1:2009 +AC:2010
EN 1041:2008 +A1:2013



**Revision History**

Revision Number	Description/Reason for Change	Document Author
01	Initial release	Ruoqian Liu, RA
02	Update new version rev.3 of the EC certificate	Ruoqian Liu, RA
03	Add WSO as additional manufacturing site	Ruoqian Liu, RA
04	Changed new format	Ruoqian Liu, RA
05	Add M7006AC of the Cardiac T1/T2 mapping and M7005DB of the DISCO for the Combo program	Ruoqian Liu, RA
06	Add M7006PB, M7006PC and M7006PD of the RFT Flex coil suit into the Compatible Coils List. Added M50022AA, M50022AB M50022AE, M50022SL, M50022SS, M50032SL, M50032SS, M50022SE, M50022CA, M50032SE, M50022CE, M50022CC, M50022CD, M50022AC, M50022AD into the Accessories and Components.	Ruoqian Liu, RA
07	Add FLO manufacturing site and remove WSO manufacturing site; Add M50022MA for MDP; Add M50022AF M50022AG for US-made Base Electric – Tesla. Add M7006LE, M7006LF, M7006LG, M7006LJ, M7006LK, M7006LM which are same parts as M7000SG GEM Flex coils 16ch –SML, only different combination for commercial offering; Remove M50022AD, M50012AG, M50012AH, M50022AB.	Ruoqian Liu, RA
08	Add M7000EZ for Flow Analysis 4.0 on Console (which was existing software function of the system software, the purpose of adding this MCAT is to enable it as an option) Add R34023AC for Standard Service Package (which was included in the Standard Service Package, but the R number was missed)	Ruoqian Liu, RA
09	Add M5001AS FLO LCCw magnet as optional.	Qiang Ding, RA
10	Update for Mulan Delta releasing. 1. Add new Mcat for LHFT 200kg, Mulan Delta. 2. Update standard list to keep consistent with EPC.	Ding Qiang, RA
11	1. Add Mulan W TJ magnet #M50022CG; 2. Add existing features: M70072AM, M70072AN and M70072AP; add existing HW configuration M50022AN as optional; 3. Add India made M50022LL, M50022AS and M50022AR; Update SIGNA Creator optional configurations: M7006AB/ M7006AD/ M7006BD/ M7006BM/ M7006BS/ M7006BH/ M7006BJ to “NO”. 4. Reorganize the Mcat# and list Unique Components by Configuration Category: Main config only, Mobile only, Bloom Only, Delta Only. 5. Update Florence site Manufacturing name.	Ding Qiang, RA
12	1. Change the revision of EN60601-1-2 and EN60601-2-33. 2. Remove the list of coils from the addendum. 3. Remove M50002MB Chinese language kit, M50002MR Japanese language kit, M50002MS Korea language kit, M50002NC Russian language kit, M50012MB Brazil Portuguese language kit, M3000LJ Magnet Chinese warning labels and M50012AJ SV25.0 to SV25.1 upgrade kit from the addendum. 4. In the addendum, add M50012HE, M50022AE, M3335MT, G50022CN, G3335JZ and G3335LJ because they are in MCR.	Huande Li, RA

**Revision History**

Revision Number	Description/Reason for Change	Document Author
	5. In the addendum, for Bloom config, add those parts for the SIGNA Creator.	
13	<ol style="list-style-type: none"><li>1. Change the SV25.2 to SV25.3.</li><li>2. Add the RoHS summary DOC2306895.</li><li>3. Add the Category number M50023AZ, M50023AC, M50023AA, M50023AG, M50023AF, M50023AR, M50023AS, M50023AQ, M50023AX, M50023AP, M50023AY in the addendum.</li><li>4. Remove "GE Healthcare Manufacturing LLC" because design transfer is not ready.</li></ol>	Huande Li, RA
14	<ol style="list-style-type: none"><li>1. Remove the config of "Mobile Only" from ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1894761.</li></ol>	Huande Li, RA
15	<ol style="list-style-type: none"><li>1. Add Florence site.</li><li>2. Add "M50023AT" and "M70012RJ Sand bag" for Signa Creator and Explorer.</li><li>3. Add "M50002HE 16ch Rear Pedestal", "M50012HE 16ch Rear Pedestal" and "M7001SE Focus" for Signa Creator.</li></ol>	Huande Li, RA