



EC 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

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GE Medical Systems, LLC

3000N. Grandview Blvd, Waukesha, WI, 53188 USA

Declare under our sole responsibility that the device:

Revolution EVO

<X-ray system, diagnostic, computed tomography, full body >

Ref.: Revolution EVO CT system Product Configuration Master

5463926-31PCM, 5463926-32PCM, 5463926-33PCM

GMDN Code: **37618**

Classification rule (93/42/EC Annex IX) : **Rule 10 Class IIb**

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.: **DOC1732895** of the product to which this declaration relates.
 - EC certificate: approval of full quality assurance system (Annex II of the Medical Devices Directive 93/42/EEC) delivered by G-MED (Notified Body No. 0459) / Certificate N°7834
 - Harmonized standards applied on the product to which this declaration relates



EN 60601-1:2006/A1:2013
EN 60601-1-2:2007/AC:2010
EN 60601-1-3:2008/AC:2010
EN 60601-1-6:2010

EN 60601-2-44:2009/A1:2012
EN 62304:2006/AC:2008
EN 62366:2008
EN ISO 10993-1: 2009/AC:2010

- For the directive 2011/65/EU (RoHS)
 - Technical Documentation/DHF Ref./ réf: **DOC1732895**, of the product to which this declaration relates

Tokyo, 13 April 2018

Tomohiro Ito
Sinner Regulatory Affairs Leader

This declaration of conformity is published to add the addendum reflecting 5463926-33PCM revision 12 according to the request of Israel and its content is made based on the DOC1568331:EC declaration of conformity dated **4 December 2017**.

**ADDENDUM TO THE DECLARATION OF CONFORMITY DOC2116907****Revolution EVO – Accessories (CT options and finished goods used with the CT System in Israel market) based on 5463926-33PCM rev12**

Medical Accessories	GEHC Catalog Designation
32CH 32SLICE	B75402RE, B77682CB, B7880CC
32CH 64SLICE	B75412RE, B77692CB, B7880CD
64CH 64SLICE	B75422RE, B77702CB, B7880CE
64CH 128SLICE	B75612RE, B77942CB, B7880CW
48KW OPTION	B75442RE, B77722CB, B7880CG
72KW OPTION	B75452RE, B77732CB, B7880CH
0.7SEC ROTATION	B75462RE, B77742CB, B7880CI
0.5SEC ROTATION	B77912AD, B77752CB, B7810LW
0.4SEC ROTATION	B75002GS, B77762CB, B7880CJ
0.35SEC ROTATION - CARDIAC	B78392AD, B77772CB, B7864KA
0.35SEC ROTATION	B75192RE, B77782CB, B7880CK
ASIR	B77802FJ, B78672CB, B7660DY
ASIR-V	B75802RE, B78682CB, B7880CM
VT2000X	B75052RE, B76492CB, B7880AD
VT2000	B75042RE, B76482CB, B7880AC
VT1700V	B75032RE, B76472CB, B7880AB
VT1700V FOR MOBILE	B78622CB
ENGLISH KYBD	B78282ML, B7590EN, B70852RT
EURO MISC KYBD	B7599ZZ
STD CABLE COLLECTOR	B76412FJ, B76052CB, B7660MR
LONG CABLE COLLECTOR	B76422FJ, B76062CB, B7660MS
REVO EVO EUROPEAN KIT	B75152RE, B76542CB
ADVANCED CARDIAC PKG	B75502RE, B7880CN
LOW DOSE CARDIAC PKG	B75862RE
CARDIAC PKG	B75512RE, B7880CO
SMARTSCORE PKG	B77472FJ, B7880AS
CARDIQ XPRESS REVEAL	B75052AE
CardIQ Xpress Reveal-OC	B7877AS
SNAPSHOT ASSIST	B75532FJ, B7877FB
SS ASSIST TEMPORAL ENHNCE	B75542FJ, B7877FA
ECG WAVE ON GANTRY	B77312FJ, B7660CJ
SSCORE PRO OC	B78372AD, B7850PL
ECG TRACE ON OC	B78402AD, B7864KC
CARD ENH FILTR	B78412AD, B7864KD
SNAPSHOT PULSE	B78462AD, B7864AA
CARDIQ SNAPSHOT	B78482AD, B7710LS
CARDEP ON THE OP CONSOLE	B7868EP
CT ANGIOGRAPHY PKG	B75542RE, B7880CR
HEAD PERFUSION PKG	B75682RE, B7880CP
MULTI ORGAN PER 4D PKG	B75532RE, B7880CQ
APPLICATION ON OC PKG	B75552RE, B7880CS
Smart MAR	B76982FJ, B77232CB, B7880MR
CT COLONO PRO3D EC	B75032AE, B7877AT
DENTASCAN	B7540LS
AVA XPRESS	B75022AE, B7877AR
AUTOBONE XPRESS	B75042AE, B7877AP
PERFUSION 4D NEURO	B75062AE, B7877AY



PERFUSION 4D MULTIORGAN	B75072AE, B7877AZ
VOLUME SHUTTLE	B78472AD, B7864AC
VOLUME HELICAL SHUTTLE	B79072AD, B7877H
WORKFLOW PKG	B75572RE, B7880CU
AWE CONNECTION	B77392FJ
EXAM SPLIT	B7864KH
XTREAM INJECTOR	B75052BE, B7716WP
ENHANCED XTREAM INJECTOR	B75062BE, B7716WR
USB BARCODE READER	B71382CA
TRACKBALL	B7877HB
2 TB USB EXT HARD DRIVE	E8000HF
ONE-STOP SCANNING	B77342FJ, B7660CF
IMAGE CHECK	B77362FJ, B7660CG
INTERVENTINAL HARDWARE	B75562RE, B7880CT
SMARTVIEW	B7868FM
SMARTSTEP	B7868WL
Rear Gantry Control Panel	B74542CA
IN ROOM MONITOR CABLE	B75202FJ
BOOM IN ROOM	B7710RN
ADAPTOR SMRTSTEP HINO	B79252AD, B7820HD
SmrtStp-Floro HW kit	B7877ZW
CT COVER STARTER KIT	E8003N
DIACOR CARBON OVERLAY VCT	E63151JE
VARIAN RPM CABLE COLLECTOR	B7716WM
Varian RPM Respiratory Gating Device	E8819KX
Ivy 7800 Cardiac Monitor Kit with IPC Cable	E80171KD
Ivy 7800 Cardiac Monitor Kit	E80171TD
Cardiac Cable Kit for IPC	E80171TB
MEDRAD Stellant D DualFlow ISI-ready on pedestal mount	E80141HA
MEDRAD Stellant D DualFlow ISI-ready on ceiling mount - 85cm post length	E80141HB
Alpha 7 Class 4 pedestal	E81101AE
Alpha 7 Class 4 ceiling	E81101AF
Alpha 7 Class 4 pedestal	E81101AG
Alpha 7 Class 4 ceiling	E81101AH
SyncOpen integration kit	E80261AM
Ulrich CT Motion PV injector on pedestal	E80261AF
Ulrich CT Motion injector - ceiling mounted	E80261AH
LOW PROFILE HEAD HOLDER	B75372CA
CORONAL HEAD HOLDER	B75342CA
CT CHILD POSITIONER	E8003S
CT Global Table 1700 Table Pad	E8004FN
CT Global Table 2000 Table Pad	E8004FP
CT Table Slicker with Cushion - 1700 Systems	E8016AZ
CT Table Slicker with Cushion - 2000 Systems	E8016AN
CT Straps, Narrow x2 540mm, 1060mm	E8004GD, E8004GG
CT Straps, Medium x2 540mm, 1060mm	E8004GE, E8004GH
CT Straps, Wide x2 540mm, 1060mm	E8004GF, E8004GJ
CT DESK	B75002CD, B78552CA
CT CHAIR	B77322CA, B7660B
BIG CABINET	B77292CA
Tube License Option	B7500SG
2nd set Manual Collector	B75692RE



Lung Cancer Screening documentation	B7900LC
10KVA PRTL UPS LTSPD PRO	E4502KY, B7999ZA
Extended cable for OC	B7877BW
Console Seismic kit	B76322CB
GANTRY DOLLY	B78502CA, B7850GD
GT table dolly	B77382CB
SMALL ROOM DOLLY	B7700SB
CARBON FIBER AXIAL HEAD HOLDER	E8004TK
EXTEND PAD	E8004TB
ARM SUPPORT	B70702CA
STRAPS AUTO TRATION	B75322CA
TABLE TRAY IV POLE	B75352CA
CATHETER BAG HOLDER	B78492CA
FOAM SPONGES	E8003DG
CHIN STRAPS	E8003DH
AXIAL HEADHLDR STRAP	E8003DJ
AXIAL HOLDER FOAM INSERT	E8004S
HEAD-KNEE PAD	E8004SE
SHOULDER ANKLE PAD	E8004SF
UW PROTOCOL EVO	B75832RE, B78792CB, B7880UW
VT2000 Replacement	B70002DA
VT2000x Replacement	B70012DA
VT Table Protection Pad	B70032DA

GE Healthcare Japan Corporation has verified the mutual compatibility of the accessories in combination with Revolution EVO and included relevant information to users with Revolution EVO instructions for use. This activity was subject to appropriate methods of internal control and inspection.