



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

GE Hualun Medical Systems, Co. Ltd
No. 1, Yong Chang North Road, Beijing Economic &
Technological Development Zone Beijing
100176, China

EU Authorized Representative

GE Medical Systems SCS
283 rue de la Minière
78530 BUC, FRANCE

Declare under our sole responsibility that the devices:

Brivo OEC 865(OEC Brivo Plus); Brivo OEC 785(OEC Brivo Essential);
Brivo OEC 715(OEC Brivo Prime)

X-ray system, diagnostic, fluoroscopic, general-purpose, mobile, digital

Ref.: see addendum

GMDN Code: **37646**

UDI-DI Code: 00195278013453, 00195278013446, 00840682115377

Class IIb according to Directive 93/42/EEC, Annex IX, rule 10

To which this declaration relates are in conformity with the requirements of the medical devices directive 93/42/EEC and the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

This conformity is based on the following elements:

- For the medical devices directive 93/42/EEC (prevailing directive)
 - Technical Documentation/DHF Ref./ réf: DOC1303941, 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 registration number: 0459) /Certificate No: N° 7846
 - harmonized standards applied on the product to which this declaration relates (see below)
- For the RoHS directive 2011/65/EU
 - Technical Documentation/DHF Ref./ réf: DOC1303941, of the product to which this declaration relates

List of harmonized standards applied for CE marking

EN 60601-1:2006/ A1:2013
EN 60601-2-43 :2010
EN1041:2008

EN 60601-1-2 :2015
EN 60601-2-28: 2010
EN 62366:2008

EN 60601-1-3:2008/ /A11:2016
EN ISO 15223-1:2016
EN ISO10993-1:2009/AC:2010

EN 60601-1-6 :2010
EN 62304:2006 /AC:2008
EN 60601-2-54: 2009

Beijing, 13rd-Oct-2021

Philip Malca
Regulatory Affairs Director

**ADDENDUM TO THE EC DECLARATION OF CONFORMITY**

Product Description	Catalog Designation
Brivo OEC 785	S20002DD, S20002GG, S20002HW, S20002JE
19" LCD Color Monitor	S20002DF
19" LCD Mono Monitor	S20002DG
Footswitch	S20002DH, S20002DJ, S20002FA, S20002FB, S20002HF, S20002HG
English Service Manual	S20002DK
DVD Burner	S20002DS
Removable grid, removable filter	S20002DT
9" Universal Film Cassette Holder for 10" x 12" (24cm x 30cm)	S10002HZ
Sony Printer	S1002JC, S10002BK, S20002HB, S20002HC, S7004GD
Tube side laser aimer	S20002DW
Video distributor for external DVI video output	S20002DZ, S20002HZ
X-Ray Tube Skin Spacer 30cm	S20002DY
II side laser aimer	S20002EZ, S20002FZ, S20002FN, S20002FT, S20002FS, S20002FR, S20002FY, S20002GA, S20002FP, S20002FW, S20002GR, S20002GS, S20002GT, S20002GW, S20002GY, S20002GZ, S20002HD
Brivo OEC 865	S20002DE, S20002GH, S20002HY, S20002JC
Footswitch	S20002DH, S20002DJ, S20002FA, S20002FB, S20002HF, S20002HG
English Service Manual	S20002DK
DVD Burner	S20002DS
Removable grid, removable filter	S20002DT
9" Universal Film Cassette Holder for 10" x 12" (24cm x 30cm)	S10002HZ
Sony Printer	S1002JC, S10002BK, S20002HB, S20002HC, S7004GD
Tube side laser aimer	S20002DW
Video distributor for external DVI video output	S20002DZ, S20002HZ
X-Ray Tube Skin Spacer 30cm	S20002DY
II side laser aimer	S20002EZ, S20002FZ, S20002FN, S20002FT, S20002FS, S20002FR, S20002FY, S20002GA, S20002FP, S20002FW, S20002GR, S20002GS, S20002GT, S20002GW, S20002GY, S20002GZ, S20002HD
Brivo OEC 715	S20002DC, S20002GF, S20002HT, S20002JB
19" LCD Color Monitor	S20002DF
Footswitch	S20002DH, S20002DJ, S20002FA, S20002FB, S20002HF, S20002HG
English Service Manual	S20002DK
DVD Burner	S20002DS
Removable grid, removable filter	S20002DT
9" Universal Film Cassette Holder for 10" x 12" (24cm x 30cm)	S10002HZ
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X-Ray Tube Skin Spacer 30cm	S20002DY
II side laser aimer	S20002EZ, S20002FZ, S20002FN, S20002FT, S20002FS, S20002FR, S20002FY, S20002GA, S20002FP, S20002FW, S20002GR, S20002GS, S20002GT, S20002GW, S20002GY, S20002GZ, S20002HD
Key components covered by this declaration of conformity	
Description	Part number
Beam Limiting Device	5417680, 5075400
Image Intensifier Assy.	5075001, 5075008, 5085917
Monoblock (Combination of X-ray Generator and tube)	Part#: 5085004 Model#: Brivo OEC 2.2A X-ray Generator Part#: 7888358(Spare part only)