



Declaration of Conformity

For the following

Product : Diagnostic X-ray System
Model(s) : XGEO GC80 and GC80
Classification: IIb

Revision: 03(See Appendix I)

We hereby declare, that the product above is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, is subject to the procedures set out in Annex II (excluding section 4) of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of SGS UK (Notified Body No.: 0120). All supporting documentation is retained under the premises of the manufacturer. The Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 50581:2012.

EN ISO 980:2008	EN 1041:2008
EN ISO 13485:2012	EN ISO 10993-1:2009
EN ISO 14971:2012	EN 60601-1:2006
EN 60601-1-2:2007	EN 60601-1-3 :2008
EN 60601-2-28:2010	EN 60601-2-54:2009
EN 62304:2006	EN 62366:2008

Manufacturer:

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30 Oct 2015

(Place and date of issue)

Gi Ho Kang/Regulatory Affairs Director

(Name and signature of authorized person)

Representative in the EU:

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Note : It is not the address of Samsung Service Centre. For the address or the phone number of Samsung Service Centre, see the warranty card or contact the retailer where you purchased your product



Appendix I

Product	Model	Classification	Declaration Date	Revision No.
Diagnostic X-ray System	GC80	I Ib	Oct. 08. 2014	00
Diagnostic X-ray System	GC80	I Ib	May. 13. 2015	01
Diagnostic X-ray System	GC80	I Ib	May. 27. 2015	02
Diagnostic X-ray System	XGEO GC80 & GC80	I Ib	Oct. 30. 2015	03