

Declaration of Conformity

For the following

Product : Diagnostic X-ray System
Model(s) : GC70, GC85A
Classification: IIb

Date of affixing CE marking: 16 January, 2015

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 DNV GL Presafe AS (Notified Body No.: 2460) by application of

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|-----------------------------|----------------------------|
| EN 15223-1:2016 | EN 1041:2008 |
| EN ISO 13485:2016 | EN ISO 10993-1:2009 |
| EN ISO 14971:2012 | EN 60601-1:2006/A1:2013 |
| EN 60601-1-2:2015 | EN 60601-1-3 :2008/A1:2013 |
| EN 60601-1-6:2010 / A1:2015 | EN 60601-2-28:2010 |
| EN 60601-2-54:2009/A1:2015 | EN 62304:2006 |
| EN 62366:2008/A1:2015 | |

and 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.

All supporting documentation is retained under the premises of the manufacturer.

**Manufacturer:**

Samsung Electronics Co., Ltd.
129, Samsung-ro, Yeongtong-gu,
Suwon-si, Gyeonggi-do, Korea

March. 20, 2019

(Place and date of issue)

Aeyoung Ha
/ Group Leader, Regulatory Affairs

(Name and signature of authorized person)

**Representative in the EU:**

Samsung Electronics GmbH
Am Kronberger Hang 6,
65824 Schwalbach am Taunus, Germany

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