

EU Declaration of Conformity

For the following

Product name : Digital Diagnostic X-ray System
Model(s) name : GC85A
Risk Class : IIb
Basic UDI-DI : 8806090DGRGC001VD

We hereby declare under our sole responsibility, that the products above are in conformity with Regulation (EU) 2017/745, is subject to the procedures set out in Annex IX (Chapters I & III) of Regulation (EU) 2017/745 under the supervision of DNV Product Assurance AS (Notified Body No.: 2460, Certificate No.: 10000459198-PA-NoMA-KOR), that the products are in conformity with Radio Equipment Directive(2014/53/EU), complying with the following standards,

EN ISO 15223-1:2021	EN 60601-1-2:2015+A1:2021
ISO 20417:2021	EN 60601-1-3:2008+A1:2013+A2:2021
EN ISO 13485:2016	EN 60601-1-6:2010+A1:2015+A2:2021
EN ISO 10993-1:2020	IEC 60601-2-54:2022
EN ISO 14971:2019	EN 62304:2006+A1:2015
EN 60601-1:2006+A1:2013+A2:2021	EN 62366-1:2015+A1:2020

that the products are in conformity with the Directive (2011/65/EU) and the amendment of Annex II (2015/863) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 63000:2018 and with the Machinery Directive (2006/42/EC) on the essential health and safety requirements.

All supporting documentation is retained under the premises of the manufacturer. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:

SRN : KR-MF-000020682
 Samsung Electronics Co., Ltd.
 129,Samsung-ro, Yeongtong-gu,
 Suwon-si, Gyeonggi-do, Korea



27.Dec. 2024

(Place and date of issue)

Subong Bae/ Group Leader, Regulatory Affairs

(Name and signature of authorized person)

Authorised Representative:

SRN: DE-AR-000007005
 Samsung Electronics GmbH
 Frankfurter Strasse 2,
 65760 Eschborn, 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

Including following components for GC85A.

No	Name as per Device Label	Identifier
1	Ceiling suspension	(SDR-OGTS80U) (SDR-OGTS80N)
2	Patient Table	(SDR-OGTA80U)
3	Wall Stand	(SDR-OGST80U) (SDR-OGST73A) (SDR-OGST73B) (SDR-OGST73C)
4	High voltage generator	(SDR-OGCA80U, GXR-82) (SDR-OGCA75A, GXR-82) (SDR-OGCA75B, GXR-52) (SDR-OGCA75C, ZR75PN80) (SDR-OGCA75D, ZR75PN50) (SDR-OGCA81A, GXR-82/52, ZR75PN80/50)
5	X-ray Tube	(E7869X) (E7252X)
6	Collimator	(SDR-OGCL80U) (SDR-OGCL83U) (SDR- OGCL81U) (SDR-OGCL83N)
7	Detector	(S4335-W) (S4343-W) (S3025-W) (S4335-AW) (S4343-AW) (FXRD-2530VAW PLUS : Marketing name: S3025- AW) (FXRD-2530VAW : Marketing name: S3025- AWM) (S4335-AWM) (S4343-AWM) (F4335-AW) (F4343-AW)
8	CIB	(SDR-OGCI80U)
9	Foot Switch	(SDR-OGSF10A/ SDR-OGSF80L for Wall Stand) (SDR-OGSF70A/ SDR-OGSF81L for Patient Table)
10	Remote Controller	(SDR-OGRC80U) (SDR-OGRC81J)
11	Wired X-ray Exposure switch	(C2U-45) (F29-9A)
12	Workstation (PC, Monitor, S/W)	-With operation S/W & Image processing S/W(S-Vue™)