

Declaration of Conformity

For the following

Product : Mobile Digital Batteries X-ray units
Model(s) : GM85
Classification: IIb

Date of affixing CE marking: 26 October, 2016

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

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/A1:2015
IEC 62366-1:2015	

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.

The manufacturer is exclusively responsible for the declaration of conformity and 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

Dec. 27, 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.

APPENDIX TO THE DECLARATION OF CONFORMITY

Product Description	Manufacturer
GM85	Samsung Electronics Co., Ltd.
Components/Accessories	
HVG	
SMG-40	DRGEM Co., Ltd.
Venus-40-M	Neusoft Medical Systems Co., Ltd.
Tube (option)	
XRR-3332X	Canon Electron Tubes & Devices Co., Ltd.
LUC-13L	LUCEM Co., Ltd.
Detector	
S4335-W	Samsung Electronics Co., Ltd.
S4343-W	Samsung Electronics Co., Ltd.
S3025-W	Samsung Electronics Co., Ltd.
S4335-AW	Samsung Electronics Co., Ltd.
S4343-AW	Samsung Electronics Co., Ltd.