

# EU Quality Management System Certificate

Certificate no.:  
10000459198-PA-NoMA-KOR

Initial certification date:  
07 March 2022

Valid Until:  
07 March 2027

This is to certify that the quality system of

**SAMSUNG ELECTRONICS CO., LTD.**

129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

SRN: KR-MF-000020682

For design, production, and final product inspection/testing of:

**Digital Diagnostic X-ray System, Digital Diagnostic Mobile X-ray System, Retrofit Kit for Digital Radiography, Application Software for Digital Diagnostic X-ray System**

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX,  
(Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:  
Høvik, 07 December 2024



For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway



**Hazem Tinawi**  
Management Representative

## jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2502580	07 March 2022
1.0	Technical Review & Certificate Issuance (Admin change - Update of Conformity assessment)	2712167	02 June 2022
2.0	Addition of new site	3157252	07 October 2024
3.0	Addition of new model Remove GR40CWC	3194031	22 November 2024
4.0	<b>EU Rep address change</b>	<b>3219312</b>	07 December 2024

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Digital Diagnostic X-ray System (The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.)	GC85A	IIb
Digital Diagnostic Mobile X-ray System (The GM85 Digital Mobile X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician.)	GM85	IIb
Digital Diagnostic X-ray System (The GF85 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications)	GF85 (GF85-3P, GF85-SP)	IIb
Retrofit Kit for Digital Radiography	GR40CW GR40CWD	IIa
Application Software for Digital Diagnostic X-ray System	Auto Lung Nodule Detection	IIa

\* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: N/A

The complete list of devices is filed with the Notified Body

#### Sites covered by this certificate

Site Name	Address
SAMSUNG ELECTRONICS CO., LTD.	129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea
SAMSUNG ELECTRONICS CO., LTD. (Gangdong site)	1077, Cheonho-daero, Gangdong-gu, Seoul, 05340, Republic of Korea

EU Representative
Samsung Electronics GmbH Frankfurter Strasse 2, 65760 Eschborn, Germany

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.