EU Quality Management System Certificate

Certificate no.:	Initial certification date:	Valid Until:
C550246	12 June 2025	12 June 2030

This is to certify that the quality system of

DRGEM Corporation

7Fl, E-B/D Gwangmyeong Techno-Park, 60 Haan-ro, Gwangmyeong-si, Gyeonggi-do, 14322
Republic of Korea

SRN: KR-MF-000017990

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

Diagnostic X-ray System, Digital diagnostic X-ray System, Mobile X-ray System, Digital Imaging System, High Voltage X-Ray Generator, Rotating Anode X-ray Tube Assembly and X-ray collimator

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

Digitally signed by Rață Sergiu
Date: 2026.05.22 10:39:41 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Place and date:
Høvik, 12 June 2025

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

C. Rajesh Kumar

Rajesh Kumar Chellappan
Management Representative

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2728259 2728261 2728264 2728265	12 June 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
High Voltage X-Ray Generator (Intended purpose: The High Voltage X-Ray Generator is intended for use in supplying high voltage to the X-ray system of the purpose of acquiring X-ray images of human anatomy for the medical diagnosis.)	High Voltage X-Ray Generator GXR-32, GXR-40, GXR-52, GXR-68, GXR-82, GXR-C32, GXR-C40, GXR-C52, GXR-U32, GXR-U40	IIb
Rotating Anode X-ray Tube Assembly (Intended purpose: The Rotating Anode X-ray Tube Assembly is intended for use in generating X-radiation within an X-ray system for medical diagnosis.)	Rotating Anode X-ray Tube Assembly DXT-8M, DXT-10M, DXT-11M, DXT-12M, DXT-14U, DXT-15U	IIb
X-ray collimator (Intended purpose: The X-ray collimator is intended for use in adjusting the irradiation area and filters within an X-ray system for medical diagnosis.)	X-ray collimator DXC-RMH, DXC-RML	IIb

Diagnostic X-ray System (Intended purpose: The Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnosis by using X-rays.)	Diagnostic X-ray System GXR-32S, GXR-40S, GXR-52S, GXR-68S, GXR-82S, GXR-C32S, GXR-C40S, GXR-C52S, GXR-U32S, GXR-U40S FDR Smart FGXR-32S, FDR Smart FGXR-40S, FDR Smart FGXR-52S, FDR Smart FGXR-68S, FDR Smart FGXR-82S FDR Smart FGXR-C32S, FDR Smart FGXR-C40S, FDR Smart FGXR-C52S FDR Smart FGXR-U32S, FDR Smart FGXR-U40S FDR Smart GXR-32S, FDR Smart GXR-40S, FDR Smart GXR-52S, FDR Smart GXR-68S, FDR Smart GXR-82S FDR Smart GXR-C32S, FDR Smart GXR-C40S, FDR Smart GXR-C52S, FDR Smart GXR-U32S, FDR Smart GXR-U40S AeroRAD-32S, AeroRAD-40S, AeroRAD-52S, AeroRAD-68S, AeroRAD-82S, AeroRAD-C32S, AeroRAD-C40S, AeroRAD-C52S, AeroRAD-U32S, AeroRAD-U40S	IIb
Diagnostic X-ray System (Intended purpose: The Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnosis by using X-rays.)	Diagnostic X-ray System DIAMOND-5B, DIAMOND-6B, DIAMOND-8B FDR Smart FGXR-Z52S, FDR Smart FGXR-Z68S, FDR Smart FGXR-Z82S	IIb

Diagnostic X-ray System (Intended purpose: The Diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnosis by using X-rays.)	Diagnostic X-ray System GXR-E20S, GXR-E25S, GXR-E32S, GXR-E40S, GXR-EC20S, GXR-EC25S, GXR-EC32S, GXR-EC40S, GXR-EC50S FDR Smart FGXR-E20S, FDR Smart FGXR-E25S, FDR Smart FGXR-E32S, FDR Smart FGXR-E40S, FDR Smart FGXR-EC20S, FDR Smart FGXR-EC25S, FDR Smart FGXR-EC32S, FDR Smart FGXR-EC40S, FDR Smart FGXR-EC50S	IIb
Digital diagnostic X-ray System (Intended purpose The Digital diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnosis by using X-rays including a digital imaging system.)	Digital diagnostic X-ray System GXR-32SD, GXR-40SD, GXR-52SD, GXR-68SD, GXR-82SD, GXR-C32SD, GXR-C40SD, GXR-C52SD, GXR-U32SD, GXR-U40SD	IIb
Digital diagnostic X-ray System (Intended purpose The Digital diagnostic X-ray System is intended for use in obtaining human anatomical images for medical diagnosis by using X-rays including a digital imaging system.)	Digital diagnostic X-ray System DIAMOND-5A, DIAMOND-6A, DIAMOND-8A	IIb
Mobile X-ray System (Intended purpose: The Mobile X-ray System is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis)	Mobile X-ray System JADE-32, JADE-40	IIb
Mobile X-ray System (Intended purpose: The Mobile X-ray System is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis.)	Mobile X-ray System TOPAZ-32D, TOPAZ-40D	IIb

Digital Imaging System	Digital Imaging System ACQUIDR	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
DRGEM Corporation	7Fl, E-B/D Gwangmyeong Techno-Park, 60 Haan-ro, Gwangmyeong-si, Gyeonggi-do, 14322, Republic of Korea
DRGEM Corporation (Factory 1)	116-59, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39377, Republic of Korea
DRGEM Corporation (Factory 2)	213, Saneopdanji-ro, Eomo-myeon, Gimcheon-si, Gyeongsangbuk-do, 39536, Republic of Korea

EU Representative
OBELIS S.A Bd. General Wahis, 53 1030 Brussels, Belgium

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 and IIb devices falling under Article 52 (4) 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.