DNV·GL

# EC CERTIFICATE

## Full Quality Assurance System

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| **9791-2017-CE-KOR-NA-PS Rev. 6.0** | **PRJC-24381-2007-MSL-KOR** | **16 April 2023** |

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, Korea

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

## Diagnostic X-Ray system and sub-components

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
**Høvik, 29 April 2020**

NORWEGIAN ACCREDITATION

**PROD 021**

For:
**DNV GL PRESAFE AS**

**Notified Body No.: 2460**

**Mariann Jeremiassen**

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
**9791-2017-CE-KOR-NA-PS Rev. 6.0**

Project No.:
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Valid Until:
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**Jurisdiction**

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Issue Date |
|---|---|---|
| 0.0 | Transfer to NB 2460 from certificate no 24108-2008-CE-NOR ver 10 | 18 May 2017 |
| 1.0 | Re-certification | 27 March 2018 |
| 2.0 | Extension in scope – new products | 10 September 2018 |
| 3.0 | Extension in scope – new products added | 14 March 2019 |
| 4.0 | Editorial change | 15 April 2019 |
| 5.0 | Extension in scope – new products added | 05 July 2019 |
| **6.0** | **Extension in scope - new products (in bold) added** | **29 April 2020** |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| 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, MXR-35 | IIb |
| Diagnostic X-ray System | GXR-32S, GXR-40S, GXR-52S, GXR-68S, GXR-82S, GXR-C32S, GXR-C40S, GXR-C52S GXR-U32S, GXR-U40S, **GXR-E20S, GXR-E25S, GXR-E32S, GXR-E40S, FDR Smart FGXR-E20S, FDR Smart FGXR-E25S, FDR Smart FGXR-E32S, FDR Smart FGXR-E40S** | IIb |
| Digital diagnostic X-ray System | DIAMOND-5A, DIAMOND-6A, DIAMOND-8A, GXR-32SD, GXR-40SD, GXR-52SD, GXR-68SD, GXR-82SD, GXR-C32SD, GXR-C40SD, GXR-C52SD, GXR-U32SD, GXR-U40SD, RADGEN ECO, RADGEN ECO PLUS | IIb |
| Digital Imaging System | ACQUIDR, AGATE-S | IIb |
| Mobile X-ray System | TOPAZ-32D, TOPAZ-40D, TOPAZ-32R, TOPAZ-40R, JADE-32, JADE-40 | IIb |
| X-ray collimator | DXC-RMH, DXC-RML | IIb |

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

| Site Name | Address |
|---|---|
| Head office | 7Fl, E-B/D Gwangmyeong Techno-Park 60, Haan-ro, Gwangmyeong-si, Gyeonggi-do,14322, Korea |
| Factory | 116-59, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39377, Korea |

**EU Representative**

Obelis s.a. Bd. Général 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

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

# Conformity declaration and marking of product

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

End of Certificate