

Declaration of Conformity

We, **DRGEM Corporation**

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

declare under our sole responsibility that the product;

Product: DIGITAL DIAGNOSTIC X-RAY SYSTEM

Model/Type: Refer to attachment 1

Classification: Class IIb Rule 10 according to Annex IX of the MDD

is in conformity with the essential requirements and provisions of Council Directive

93/42/EEC as amended by 2007/47/EC

is in conformity with the harmonized standards EN60601-1:2006/A1:2013 , EN60601-1-2:2015,
EN60601-1-3:2008/A11:2016, EN60601-1-6:2010/A1:2015, EN60601-2-28:2010, EN60601-2-
54:2009/A1:2015, ENISO15223-1:2016, ENISO14971:2012, ENISO13485:2016, EN62366:2008,
EN62304:2006

is subject to the procedure set out in Annex II (Exclusion section 4) of Directive
93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body **2460**,
DNV GL Presafe AS: Veritasveien 3 1363 Høvik Norway

Date of validity: until validity of current certificate of Directive 93/42/EEC

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a.

Registered Address:

53 Bd. Général Wahis
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
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Representative: Mr. Gideon ELKAYAM



Manufacturer :

DRGEM Corporation

Place and date:

Gwangmyeong, Korea,
July 19, 2019

A handwritten signature in black ink, appearing to read 'JBY Park', is written over a horizontal line.

Jung-Byung Park / President

Attachment 1

Product Description	Product Name	Class
Digital Diagnostic X-ray System	<ul style="list-style-type: none">• GXR-32SD• GXR-40SD• GXR-52SD• GXR-68SD• GXR-82SD• GXR-C32SD• GXR-C40SD• GXR-C52SD• GXR-U32SD• GXR-U40SD	IIb

DRGEM

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