

# EU Declaration of Conformity

Manufacturer	DRGEM Corporation 7FI E-B/D Gwangmyeong Techno-Park 60, Haan-ro, Gwangmyeong-si, Gyeonggi-do, Republic of Korea, 14322 SRN(Single Registration Number): KR-MF-000017990
Authorized Representative	Obelis s.a. Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: <a href="mailto:mail@obelis.net">mail@obelis.net</a> SRN: BE-AR-000000106
Notified body	DNV Product Assurance AS supervision of Notified Body Veritasveien 1 1363 Høvik Norway NB Number: 2460
Conformity assessment	Annex IX, excl. Chapter II in Regulation (EU) 2017/745
Certificate No	C550246
Product	Basic UDI-DI: 88000111DSGSD4000PB Product Name: Digital diagnostic X-ray System Model: GXR-32SD, GXR-40SD, GXR-52SD, GXR-68SD, GXR-82SD, GXR-C32SD, GXR-C40SD, GXR-C52SD, GXR-U32SD, GXR-U40SD
Risk Classification	Class IIb by Rule 10 according to Annex VIII of Regulation (EU) 2017/745
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.
<p>The declaration is issued under the sole responsibility of the <b>DRGEM Corporation</b>.</p> <p>We here declare that the above mentioned products comply with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and Machinery Directive 2006/42/EC, Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU &amp; (EU) 2015/863.</p>	

**Place and date:** Gwangmyeong, Republic of Korea,  
June 12, 2025

**Name and Function:** Jung-Byung Park / President  
**On behalf of DRGEM Corporation**



**Signature:**