EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 10001-2017-CE-KOR-NA-PS Rev. 9.0 Project No.: PRJC-51732-2008-MSL-KOR Valid Until: 27 May 2024

This is to certify that the quality system of:

GENORAY Co., Ltd.

(Sangdaewon-dong, Byucksan Technopia), 512, 560, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

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

X-ray Systems

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, 29th April 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Hazem Tinawi
Technical Reviewer

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
	Original NB 0434 Certificate No. 54283-2009-CE-KOR-NA Rev.11.0	25 January 2017
0.0	Transfer to NB 2460 New model added OSCAR Model deletion_MX-300, VOLUX 9, VOLUX 21, VOLUX 21C	08 June 2017
1.0	Scope extension new model (PORT-X IV) added, new brand name (PORT-X II NEW) added	09 April 2018
2.0	Alias model added and model deletion of PACS	03 August 2018
3.0	Editorial change	10 December 2018
4.0	Re-Certification Alias model added and model deletion	11 June 2019
5.0	Editorial change in page number	16 July 2019
6.0	Change in model name from PAPAYA 3D Plus Premium to PAPAYA 3D Premium Plus	03 April 2020
7.0	Alias model name added OSCAR 15 (Unique FD), OSCAR (OSCAR Prime / OSCAR Classic (Unique Class)), ZEN-7000 (ZEN-CX3090, Unique Premium), ZEN-2090 Pro (ZEN-CX2090, ZEN-2090 Turbo, XENO-360)	1 July 2020
8.0	Addition to new site, and Scope extension to new models - PORT-X IVe (ZEN-PX4e), PAPAYA 3D, PAPAYA 3D Plus (VOLUX 55)	23 March 2021
9.0	**Scope extension to new product (Intra-oral dental X-ray system - DVAS (DVAS-C, DVAS-W, DVAS-M)) added**	**29th April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Portable X-ray system	PORT-X II (EZX-60, ZEN-PX2), PORT-X III (ZEN-PX3, PORT-X II NEW), PORT-X IV (ZEN-PX4) PORT-X IVe (ZEN-PX4e)	IIb
Fluoroscope X-ray system	ZEN-2090 Pro (ZEN-CX2090, ZEN-2090 Turbo, XENO-360), ZEN-5000, ZEN-7000 (ZEN-CX3090, Unique Premium), OSCAR 15 (Unique FD), OSCAR (OSCAR Prime/OSCAR Classic (Unique Class))	IIb
Digital Panoramic X-ray system	PAPAYA (GDP-1)	IIb
Digital Panoramic & Cephalometric X-ray system	PAPAYA Plus (GDP-1C, VOLUX 29)	IIb
Mammographic X-ray system	MX-600	IIb
Diagnostic computed tomography limited view field X-ray system	PAPAYA 3D PAPAYA 3D Plus (VOLUX 55) PAPAYA 3D Premium PAPAYA 3D Premium Plus	IIb
Digital Mammographic X-ray System	DMX-600	IIb
Intraoral Imaging System	PortView (GIX-1)	IIa
Intra-oral dental X-ray system	**DVAS (DVAS-C, DVAS-W, DVAS-M)**	**IIb**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Manufacturing Site	(Sangdaewon-dong, Byucksan Technopia), 512, 560, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
R&D Site	301 morandreamcity, Dunchon-daero 80 street 3-15, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

Obelis s.a. Boulevard 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 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. the Notified Body 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.

End of Certificate