

**Date : July 1, 2021**

## **Manufacturer's Authorization Form**

**To: United Nations Development Programme**

**WHEREAS EcoRay Co., Ltd. who are established and reputable manufacturers of Ecoview9 Plus Digital Radiography System, having factories at 60-10, Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollanam-do, Korea 57248.**

do hereby authorize **FCPC "DataControl" SRL**, 20 Melestiu Street, MD-2001, Chisinau, Republic of Moldova, to submit a bid, and subsequently negotiate and sign the Contract with you against Tender Ref.no.: ocds-b3wdp1-MD-1623402942659 from 13.07.2021 organized by the: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE** concerning medical products manufactured by us.

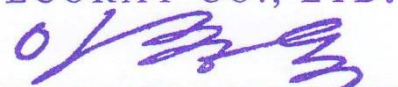
We hereby extend our full guarantee and warranty for the goods offered for supply by the above firm against this Invitation for Bids.

We guarantee the quality and the performances of the offer products and authorize **FCPC "DataControl" SRL** to assure for the respective products, the fulfilment of the obligations under the supplying contract referring to the goods.

Sincerely yours,

DongWoog Lee / President

**ECORAY CO., LTD.**



**LEE DONG WOOG / President**

# ECOVIEW 9 PLUS

General Rad Room DR system Data Sheet



## Ecoview9 Plus (introduction)

The Ecoview 9 Plus is a solution with optimized design with ergonomics and durable mechanics to serve with smooth, quick and easy operations for reliable examinations in the radiographic rooms.

Its standard configuration consists of:

	Standard configuration
HFG	50kW
POWER OUTPUT	150 kV
Max. mA	630 mA
X-RAY TUBE	0.6/1.2mm, 300KHU
LINE VOLTAGE	380VAC, 50/60Hz, three phase
TUBE STAND	Floor mounted tube stand
BUCKY TABLE	4 way top floating bucky table
BUCKY STAND	Upright bucky stand
O/P CONSOLE	LCD OP console



The system can be configured to the desired user's specifications combining with the available options.

Available options and specifications for each device and parts are described below.

Refer to each section described about required options and specifications.

## High Frequency Generator




It makes us unique. ECORAY provides different types of generators solution for users. Since 1990, ECORAY brings steady and durable generators developed from its own technology providing a better image quality with reduced patient dose and extended X-ray tube lifetime. ECORAY's generators can be classified in two groups, 40 kHz frequency and 300 kHz frequency generators.

### High frequency generator specifications




CATEGORY	32kW	40kW	50kW		65kW	80kW
KV range	40-125kV	40-125kV	40-150kV	40-150kV	40-150kV	40-150kV
Radiographic mA range	10~400	10~500	10~630	10~800	10~800	10~1,000
Exposure Time Range Accuracy	0.001 - 6 seconds (81 steps) ±2%					
Frequency	40kHz			Max. 300kHz		
mAs Range	0.1 ~ 400	0.1 ~ 500	0.1 ~ 630	0.1 ~ 800	0.1 ~ 800	0.1 ~ 1,000
High Voltage Ripple(TYP)	<1kV@100kV					
Automatic Exposure Control	Optional (up to 2 chambers)					
Power Supply Unit (PSU)	Optional (battery/capacitor type)					
Anatomical Programming	288 APR			1,290 APR		
OP Console	LCD OP console / Touch screen OP console (Option)		LCD OP console			
Line Voltage (phase)	220-230VAC, 50/60Hz, Single Phase		380VAC, 50/60Hz, Three phase			
Automatic Line compensation	± 10%					
Weight	110KG			130KG		

## HF Generators

### High frequency generator appearance

		
32/40kW/ 50kW(630mA)	50kW(800mA)/ 65kW/80kW	32/40kW Capacitor bank

### OP console specifications

CATEGORY	LCD OP console	Touch screen OP console	LCD OP console
Generator type	For 40kHz frequency generators		For 300kHz frequency generators
Operation	Membrane key touch	Touch screen & membrane key touch	Membrane key touch
Anatomical programming	288 APR		1,290 APR
AEC	AEC control (3 field ion chambers) (Option)		
DAP	DAP display (Option)		
Interfaces	HFG control serial port, Hand switch port, DR trigger LAN port, AEC chamber serial port, DAP serial port		
Appearance			

## X-ray Tubes

ECORAY uses the worldwide Canon brand tubes. These tubes are reliable and robust with high efficient output for daily radiographic operations.

Toshiba tubes have rotating anode with housing assembly for the purpose of general diagnostic X-ray procedures and use specially processed Rhenium-tungsten faced molybdenum targets.

### X-ray tube specifications

CATEGORY	E7239X	E7884X	E7252X	E7254X	E7869X
kV range	40-125	40-150	40-150	40-150	40-150
Small focus & max. energy	1.0mm/21kW	0.6mm/22kW	0.6mm/27kW	0.6mm/40kW	0.6mm/40kW
Large focus & max. energy	2.0mm/53kW	1.2mm/54kW	1.2mm/75kW	1.2mm/102kW	1.2mm/100kW
Anode speed (RPM@ 50/60/180Hz)*	2,700/3,200/-		2,700/3,200/9,700		
Target angle	16°	12°	12°	12°	12°
maximum available mA @ Small focus*	350mA	300mA	400mA	500mA	500mA
maximum available mA @ Large focus*	600mA	700mA	1,000mA	1,000mA	1,000mA
Anode Heating Unit	140kHU	300kHU	300kHU	400kHU	600kHU
Anode cooling rate	667HU/sec	1,226HU/sec	667HU/sec	1,664HU/sec	2,465HU/sec
Tube housing heating unit	1,250kHU	1,250kHU	1,250kHU	1,339kHU	1,600kHU
Tube housing cooling rate	15kHU/min	15kHU/min	15kHU/min	16kHU/min	18kHU/min
Weight	16kg	16kg	18kg	20kg	24kg

## Tube stand (Floor mounted)

The tube stand is a mechanical device where the X-ray tube is fixed and allows to place the tube around depending on the examination positions and anatomical body parts.

These stands generally come in 2 different designs, floor mounted and ceiling suspended tube stands.

### Floor mounted tube stand specifications

CATEGORY	SPECIFICATIONS
Type:	Manual, vertical, and longitudinal movement
Floor rail size length:	Approx. 2,500mm
Longitudinal tube stand travel:	Approx. 2,000mm
Transverse travel:	260mm
Vertical tube arm travel:	Approx. 1,500mm (400 ~ 1,900mm from ground level to focal spot)
X-ray tube rotation:	+/- 180° (detents at +90° ~ -90°)
Tube stand column rotation:	+/- 180° (detents at +90° ~ -90°)
Locks:	Electromagnetic brakes
Tube arm controls:	Longitudinal, vertical, and rotational lock control buttons



## Tube stand (Ceiling suspended)

### Ceiling suspended tube stand specifications (manual operated)

CATEGORY	SPECIFICATIONS
Type	Manual operated
Weight	125kg
Rail size	Upper rail : 4,000mm (depends on the rail length) Lower rail : 3,000mm (depends on the rail length)
Longitudinal travel	Approx. 3,000mm or more (depends on the ceiling rail length)
Transverse travel	Approx. 2,000mm or more (depends on the ceiling rail length)
Vertical tube travel:	Approx. 1,500mm (2400mm with full extended, 900mm at fully compressed)
X-ray tube rotation:	+/- 180° (detents at +90° ~ -90°)
Tube stand column rotation:	+/- 180° (detents at +90° ~ -90°)
Locks:	Electromagnetic brakes
Tube arm controls:	Longitudinal, transverse, vertical, and rotational lock control buttons



## Bucky Table (floating table)

The table bucky is used when a patient needs to lay down for radiographic examinations.

Generally, the top table is 4 way floating covering a wide examination area for examination without moving the patient. A flexible table ensures easy positioning and is suitable for all body types.

The table bucky offers a foot controller to provide an optimal working environment.

4 way top floating bucky table

CATEGORY	SPECIFICATIONS
Dimension :	2,200 x 800 x 690(H) mm
Table top composition :	Melamine Laminated structure
Table top-to-film distance:	Approx. 75 mm
Table top Al. equivalence :	<0.8mm Al at 100kVp
Table top weight limit :	250kg
Longitudinal travel :	Approx. ±400 mm
Transverse travel	Approx. ±150 mm
Buck travel	Approx. ±200 mm
Table locks :	Electromagnetic brakes
Table lock controls:	Foot controller
Table bucky:	Oscillating grid
Grid	Ratio: 10:1, 103 lines/inch (oscillating)
Cassette size :	Adjustable up to 17 x 17 inches



## Bucky Table (elevating)

Elevating bucky table (motorized elevation)

CATEGORY	SPECIFICATIONS
Dimension of Tabletop	2,200 x 800 x 510~840(H) mm
Table top composition :	Melamine Laminated structure
Table top-to-film distance:	Approx. 75mm
Table top Al. equivalence :	<0.8mm Al at 100kVp
Table top weight limit :	250kg
Longitudinal travel :	Approx. ±400 mm
Transverse travel	Approx. ±150 mm
Vertical travel	Approx. 340mm(motorized movement)
Up/down speed	Up : 16mm/sec, Down : 20mm/sec
Bucky travel	Approx. ±200 mm
Table locks :	Electromagnetic brakes
Table lock & elevation controls:	Foot controller
Table bucky:	Oscillating
Grid	Ratio: 10:1, 103 lines/inch (oscillating)
Cassette size :	Adjustable up to 17 x 17 inches





## Wall Bucky Stand

The upright bucky stand features a slender column design with smooth, vibration free movement with easy and accurate positioning.

The extensive vertical travel allows for a full range of upright radiographic studies from skull to lower extremities.

The cassette or detector can be inserted in the bucky from either left or right side (selectable on installation).

Upright bucky stand (manual operated)

CATEGORY	SPECIFICATIONS
Standard type:	Floor mounted, manual operated
Bucky:	Oscillating grid
Vertical Bucky travel :	1,500 mm (400~1,900mm from the ground to bucky center)
Vertical movement :	Manual, counterbalanced
Front plate to film distance:	Approx. 50 mm
Cassette sizes:	Adjustable up to 17 x 17 inches
Grid:	Ratio: 10:1, 103lines/inch (oscillating)
Bucky front Al. equivalence:	<0.8mm Al at 100kVp
Locks:	Electromagnetic brakes
Lock controls:	Foot controller
Accessories:	Front patient holder on both sides and upper holder



## Collimator

The purpose of the multileaf collimator is to collimate exactly the radiation beam emerging from the X-ray tube assembly onto the size of the object to be displayed.

CATEGORY	SPECIFICATIONS
Collimator type:	Manual square filed X-ray collimator
Field lamp:	LED lamp 24VAC 1A / 24VDC 1A
Lighting timer :	30 sec (auto off)
Average luminosity:	280-160 lux at SID 100 cm
Front plate to film distance:	Approx. 50 mm
Inherent filtration:	1.2mm aluminum
Max. X-ray filed:	48cm x 48cm at SID 100cm
Option:	Measuring tape

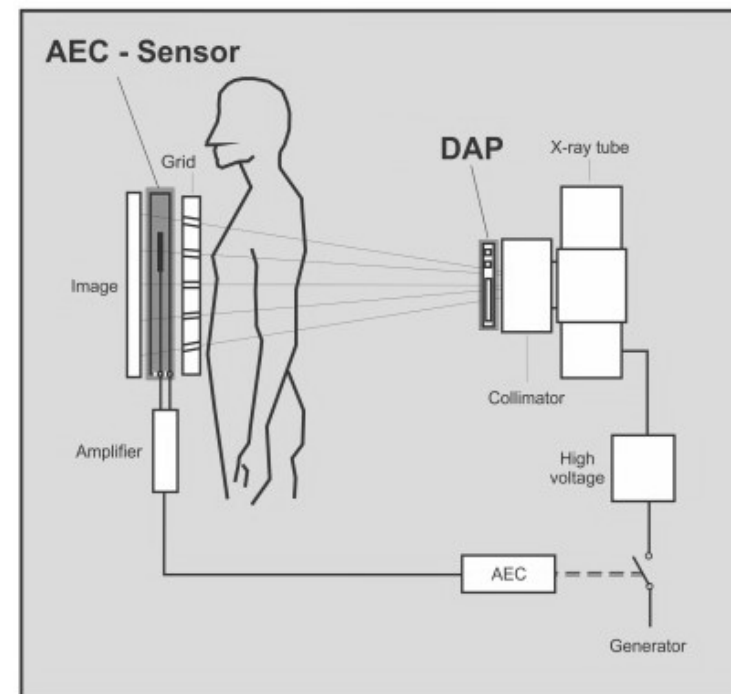


## Optional Items

### ✓ AEC, Auto Exposure Control

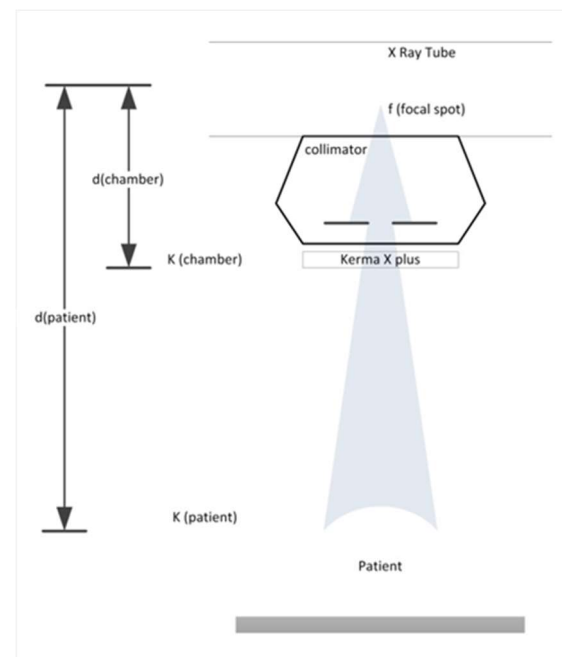
SSMC 601 (Claymount)

The SSMC 601 is placed between the patient and the imaging device (film, detector) in order to detect the actual dose value for the automatic exposure control (AEC) an error free image is guaranteed even at low kV. Its attenuation factor is very low. X-ray scattering has been brought back to the bare minimum, to improve the brightness of the image.



### ✓ DAP, Dose Area Product

RayDose-VI is a rectangular shape of device which measuring electronic circuit is embedded. It can be used with an outer controller as a set (RayDose-VII) or used without any controller (RayDose-VI). It is mounted to collimator of X-ray device to indicate radiation dose which is radiated to the patient as unit of  $\mu\text{Gym}^2$ . According to the setting, it can measure in  $0.1 \mu\text{Gym}^2$  or  $0.01\mu\text{Gym}^2$  unit, which can be changed by user.



Important: the AKP chamber must frame the radiation field at all times.

**Proof  $KA(\text{patient}) = KA(\text{chamber})$**

(1)

$$\frac{\text{area}(C)}{\text{area}(P)} = \frac{d^2_C}{d^2_P}$$

By inverse square law.

(2)

$$\frac{\text{kerma}(P)}{\text{kerma}(C)} = \frac{\text{Distance}(C)^2}{\text{Distance}(P)^2}$$

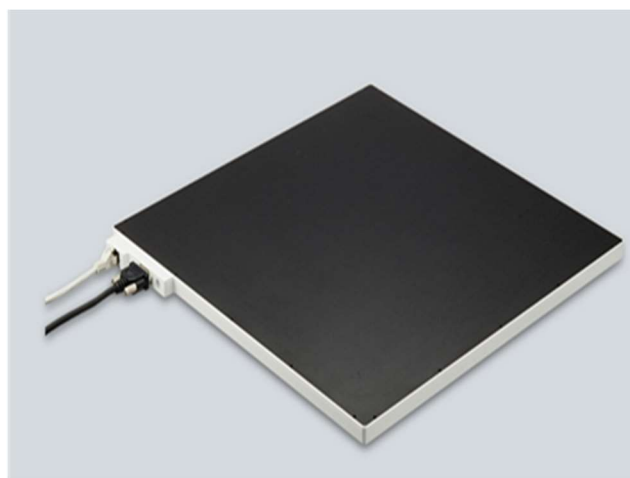
**combining 1 & 2**

$$\text{kerma}(P) \times \text{area}(P) = \text{kerma}(C) \times \text{area}(C)$$



## Workstation (DR)

CPU	Intel® Core™ i5 3.5GHZ
RAM	8GB Non-ECC DDR3 1600MHz SDRAM
Hard Drive	1000 GB
CD-R/W	16X DVD+/-RW Drive
Graphic Card	Intel® HD Graphic 2500
Operating System	Windows® 10 Professional 64 bit (English)
Monitor	23" IPS LCD Monitor
DR Software	Ecoview Image Acquisition Software (DICOM 3.0 compatible)
X-ray controlled by PC	



← 1717 Wired FPD

3643 Wireless FPD →



## Flat Panel Detector for DR solution (DR)

Flat Panel Detectors (FPD) are used in DR solutions. These detectors are more sensitive and faster than conventional film. Their sensitivity allows a lower dose of radiation for a given image quality than film. They are lighter, far more durable, smaller in volume, more accurate, and have much less image distortion than image intensification detectors and can also be produced in larger sizes.

The FPD can be combined depending on user's necessities. The system can be configured with one wireless FPD, two fixed FPD, one fixed and one wireless FPD, etc.

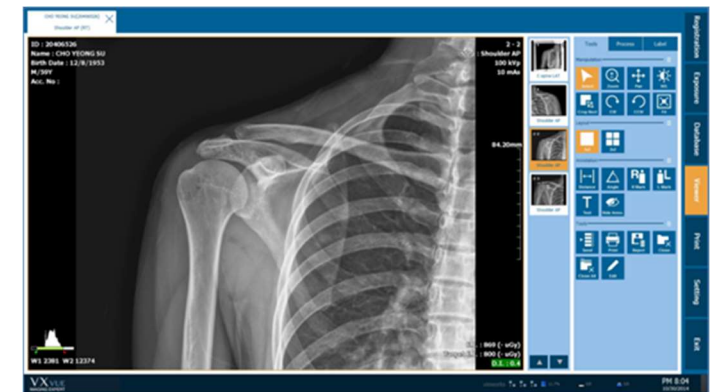
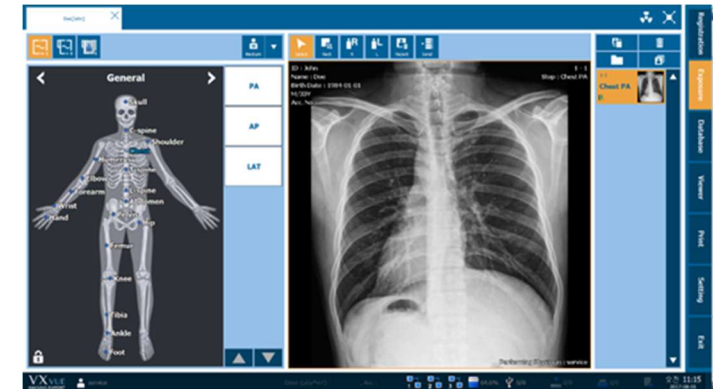
FPD's are used together with acquisition software to display digitally the obtained image. Therefore, generally they are operated with a workstation.

### Flat panel detector specifications

CATEGORY	1717 VB/VA	3643VAW/VAW PLUS Battery type
Sensor type:	Amorphous Silicon with TFT	
Scintillator type	GdOx / CsI	CsI
Total pixel matrix	3,072 X 3,072 pixels	2,560 x 3,072 pixels
Total pixel area	430 x 430 mm	358 x 430 mm
Pixel pitch	140 $\mu$ m	
Effective pixel matrix	3,048 x 3,048 pixels	2,536 x 3,048 pixels
A/D conversion	16 bits	16 bits
Spatial Resolution	3.5lp/mm	
Image Acquisition time	2 sec	3 sec
Energy range	40~150 kV	
Trigger mode	Manual mode / Auto trigger mode	
Dimensions	460 x460 x 15.5(H) mm	384 x 460 x 15(H) mm
Weight	4.5 kg	2.95-3.3 kg
Data Transmission rate	Max. 1Gbps	1 Gbps Ethernet / 300Mbps wi-fi

- DICOM 3.0 Compliance
- DICOM Work list SCU
- DICOM Storage SCU
- CD Archiving
- Integrated any generator control interface, direct control of x-ray generator with software
- With positive and negative image capturing
- Real time auto window width and window position adjustment with various contrast equalization
- Real time auto ROI resizing/ edge enhancement/ mirroring/ rotation/ auto-analysis flexible LUT
- Overlay information display (patient info./examination info./ equipment info./image info.)
- Black and white reversal/ image zooming/ translating/ magnified display/ image frequency filter
- Interested area display / original size display / full screen display/ image merge function
- Histogram display of interested areas, window width and window position adjustable
- Noise reduction, image enhancement, background filtering, latitude/contrast/edge/fixed enhancement
- Degrees adjustable according to different parts
- Image marking functions, including direct lines, rectangles, polygons, arrows and word
- **High Quality Diagnostic Images**

With our advanced DR detector technology achieves clear and high resolution diagnostic images. The Amorphous Silicon (a-Si) Flat Panel Detector, the core component, contains over 9 million pixels. The detector also features an expansive 16,000 dynamic ranges, enabling capture of images that would otherwise appear over or underexposed on conventional film. Images are displayed in 14 bits grayscale (16,384 gradations) to ensure the visibility of subtle contrast.



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### High frequency generator specifications




CATEGORY	32kW	40kW	50kW		65kW	80kW
KV range	40-125kV	40-125kV	40-150kV	40-150kV	40-150kV	40-150kV
Radiographic mA range	10~400	10~500	10~630	10~800	10~800	10~1,000
Exposure Time Range Accuracy	0.001 - 6 seconds (81 steps) ±2%					
Frequency	40kHz			Max. 300kHz		
mAs Range	0.1 ~ 400	0.1 ~ 500	0.1 ~ 630	0.1 ~ 800	0.1 ~ 800	0.1 ~ 1,000
High Voltage Ripple(TYP)	<1kV@100kV					
Automatic Exposure Control	Optional (up to 2 chambers)					
Power Supply Unit (PSU)	Optional (capacitor type)					
Anatomical Programming	288 APR			1,290 APR		
OP Console	LCD OP console / Touch screen OP console (Option)		LCD OP console			
Line Voltage (phase)	220-230VAC, 50/60Hz, Single Phase		380VAC, 50/60Hz, Three phase			
Automatic Line compensation	± 10%					
Weight	110KG			130KG		

## HF Generators

### High frequency generator appearance

		
32/40kW/ 50kW(630mA)	50kW(800mA)/ 65kW/80kW	32/40kW Capacitor bank

### OP console specifications

CATEGORY	LCD OP console	Touch screen OP console	LCD OP console
Generator type	For 40kHz frequency generators		For 300kHz frequency generators
Operation	Membrane key touch	Touch screen & membrane key touch	Membrane key touch
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Appearance			



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Large focus & max. energy	2.0mm/53kW	1.2mm/54kW	1.2mm/75kW	1.2mm/102kW	1.2mm/100kW
Anode speed (RPM@ 50/60/180Hz)*	2,700/3,200/ -		2,700/3,200/9,700		
Target angle	16°	12°	12°	12°	12°
maximum available mA @ Small focus*	350mA	300mA	400mA	500mA	500mA
maximum available mA @ Large focus*	600mA	700mA	1,000mA	1,000mA	1,000mA
Anode Heating Unit	140kHU	300kHU	300kHU	400kHU	600kHU
Anode cooling rate	667HU/sec	1,226HU/sec	667HU/sec	1,664HU/sec	2,465HU/sec
Tube housing heating unit	1,250kHU	1,250kHU	1,250kHU	1,339kHU	1,600kHU
Tube housing cooling rate	15kHU/min	15kHU/min	15kHU/min	16kHU/min	18kHU/min
Weight	16kg	16kg	18kg	20kg	24kg

# EC Certificate Full Quality Assurance System

Certificate No.:  
**12966-2018-CE-KOR-NA-PS Rev. 1.0**

Project No.:  
**PRJC-25089-2007-MSL-KOR**

Valid Until:  
**14 November 2023**

This is to certify that the quality system of:

**ECORAY Co., Ltd.**

**60-10, Nanosandan 5-ro, Nam-myeon, Jangseong-gun, Jeollanam-do, Korea**

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

**Diagnostic X-ray System**

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, 14 March 2019**



Notified Body No.: 2460

For:  
**DNV GL PRESAFE AS**



**Palani Damodharan**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



# EC Certificate

## Full Quality Assurance System

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**12966-2018-CE-KOR-NA-PS Rev. 1.0**

Project No.:  
**PRJC-25089-2007-MSL-KOR**

Valid Until:  
**14 November 2023**

### 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	Original Certificate	14-11-2018
1.0	Change in EU Representative	14-03-2019

Products covered by this Certificate:

Product Description	Product Name	Class
Diagnostic X-ray System	• HF-525Plus	IIb
Digital Radiographic X-ray System	• EcoView9 Plus	IIb
Generator	• F40 (Add Model : F32)	IIb
Generator	• ECORAD75 (Add Model : ECORAD32, ECORAD40, ECORAD50, ECORAD65)	IIb

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
ECORAY Co., Ltd.	60-10, Nanosandan 5-ro, Nam-myeon, 57248, Jangseong-gun, Korea

### EU Representative

OBELIS S.A  
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**12966-2018-CE-KOR-NA-PS Rev. 1.0**

Project No.:  
**PRJC-25089-2007-MSL-KOR**

Valid Until:  
**14 November 2023**

### 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

# Management System Certificate

Certificate No.:  
**9762-2017-AQ-KOR-NA-PS Rev. 1.0**

Project No.:  
**PRJC-25089-2007-MSL-KOR**

Initial Certification Date:  
**23 JULY 2017**

Valid Until:  
**11 JANUARY 2022**

This is to certify that the management system of:

**ECORAY Co., Ltd.**

60-10, Nanosandan 5-ro, Nam-myeon,  
052-748 Jangseong-gun  
Korea

Complies with the requirements of:

**ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, Manufacture, Distribution, Sales, Installation and Servicing of  
Diagnostic X-ray Systems**

Place and Date:  
**Høvik, 14 January 2019**



For:  
**DNV GL PRESAFE AS**

*Tone Kolpus*

**Tone Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.