



EC Certificate Full Quality Assurance System

Certificate No.:
9756-2017-CE-KOR-NA-PS Rev 2.0

Project No.:
PRJC-25028-2007-MSL-KOR

Valid Until:
12 OCTOBER 2019

This is to certify that the quality system of:

Vieworks Co., Ltd.

41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055
Republic of Korea

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

Digital Imaging System & PACS

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a
and Annex II excluding section 4 (Module H2) 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.

SAO Y BẢN CHÍNH



**Giám Đốc
NGUYỄN TRUNG TÍN**

Place and Date:
Høvik, 04 April 2018



For:
DNV GL NEMKO PRESAFE AS

Villy Rønneberg

The Certificate has been digitally signed.
See 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.



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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	Supersedes DNV GL (NB 0434) Certificate No. 51689-2009-CEKOR-NA 9.0 following transfer of notified body functions to DNV Nemko Presafe AS (NB 2460) and Scope Extension_new model added (in bold)	2017-04-26
1.0	Extension in scope - new products added	2017-11-24
2.0	EU Rep change, address change in writing	2018-04-04

Products covered by this Certificate:

Product Description	Product Name	Class
Maxxray	RXDN-6000D (Detector) Maxxvue (Imaging processor & Viewer) RXDN-6000P-15A	IIb
QXR-9	RXDN-7100D-HC RXDN-7100D-VC RXDN-7100D-HA RXDN-7100D-VA RXDN-6000P-15A RXDN-USB2M QXvue	IIb
SlimPac II	Camera Head RCMF-1015H-200, RCMF-1015H-600, RCMF-1035H SCU RCMF-1025S, RCMF-1035S S/W Slimpac II RF, Slimpac II DSA	IIb
VIVIX-S	Flat Panel Detector FXRD-1717SA, FXRD-1717SB, FXRD-1417SA, FXRD-1417SB, FXRD-1417WA, FXRD-1417WB Power Supply Unit FXRP-01A, FXRP-01B System Control Unit FXRS-02A, FXRS-03A, FXRS-04A, FXRP-02A Image Acquisition S/W VXvue	IIb

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Digital Imaging System	Flat Panel Detector FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW, FXRD-1012NBW, FXRD-1717NA, FXRD-1717NB, FXRD-1717NAW, FXRD-1717NBW, FXRD-1417NAW, FXRD-1417NBW System Control Unit FXRS-02A, FXRS-03A, FXRS-04A, FXRP-02A Image Acquisition S/W VXvue	IIb
PACS	QXLink	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055 Republic of Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium





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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

