EC Certificate
Full Quality Assurance System

Digitally signed by Botnaru Andrei
Date: 2022.08.29 13:50:59 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate No.:
9756-2017-CE-KOR-NA-PS Rev. 5.0

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

Valid Until:
27 May 2024

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 and Mammography 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, 09 October 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Palani Damodharan

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
3.0	Extension in scope – new products added	2018-05-24
4.0	Extension in scope – new products added (in bold)	2019-07-03
5.0	**Re-certification and Mammography system added**	**2019-10-08**

Products covered by this Certificate:

Product Description	Product Name	Class
Digital Imaging System	SlimPac II • Camera Head: RCMF-1015H-200, RCMF-1015H-600, ECMF-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 • Imaging Acquisition S/W: VXvue	
	VIVIX-S 1012N • Flat Panel Detector: FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW, FXRD-1012NBW • System Control Unit: FXRS-02A, FXRS-03A, FXRS-04A, FXRP-02A • Imaging Acquisition S/W: VXvue	
	VIVIX-S 1717N • Flat Panel Detector: FXRD-1717NA, FXRD-1717NB, FXRD-1717NAW, FXRD-1717NBW • System Control Unit: FXRS-02A, FXRS-03A, FXRS-04A, FXRP-02A • Imaging Acquisition S/W: VXvue	
	VIVIX-S 1417N • Flat Panel Detector: FXRD-1417NAW, FXRD-1417NBW • System Control Unit: FXRS-02A, FXRS-03A, FXRS-04A, FXRP-02A • Imaging Acquisition S/W: VXvue	
	VIVIX-S 1717V • Flat Panel Detector: FXRD-1717VA, FXRD-1717VB • IO BOX: FXRI-01A • Imaging Acquisition S/W: VXvue	
	VIVIX-D • Flat Panel Detector: FXDD-1717GA, FXDD-1212GA, FXDD-0909GA, FXDD-1012CHA • System Control Unit: FXDS-02A • Imaging Acquisition S/W: Slimpac II Plus	
	VIVIX-S 1751S • Flat Panel Detector: FXRD-1751SB • System Control Unit: FXRP-01A, FXRP-01B	
	VIVIX-S VW • Flat Panel Detector: FXRD-2530VAW, FXRD-2530VAW PLUS, FXRD-3643VAW, FXRD-3643VAW PLUS, FXRD-4343VAW, FXRD-4343VAW PLUS • Imaging Acquisition S/W: VXvue	
	VIVIX-S FW	

	• Flat Panel Detector: FXRD-2530FAW, FXRD-3643FAW, FXRD-4343FAW • Imaging Acquisition S/W: VXvue	
PACS	• QXLink	IIa
Mammography System	• **VDMS-1000B, BREGINE-MS1000B**	**IIb**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Vieworks Co., Ltd.	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