Declaration of Conformity

I. Manufacturer

Name	Vieworks Co., Ltd.	
Address	**Headquarter**	41-3, Burim-ro 170beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14055, Republic of Korea
	Hwaseong Site	25-7, Jeongnamsandan 2-gil, Jeongnam-myeon, Hwaseong-si, Gyeonggi-do, 18514, Republic of Korea
SRN	KR-MF-000020017	

II. European Representative

Name	Obelis s.a.
Address	Boulevard Général Wahis, 53, 1030 Brussels, Belgium
SRN	BE-AR-000000106

III. Device Information

Device Name	Digital Imaging System		Image Acquisition Software
Basic UDI-DI	880939433VIVIXS1717V2Y	880939433VIVIXSVW2H	880939433VXvue8X
Brand Name	VIVIX-S 1717V	VIVIX-S VW	VXvue
REF Numbers (Model Names)	FXRD-1717VA FXRD-1717VB	FXRD-2530VAW FXRD-2530VAW PLUS FXRD-3643VAW FXRD-3643VAW PLUS FXRD-4343VAW FXRD-4343VAW PLUS	VXvue
Classification	Class IIa by Rule 10 of Annex VIII, Regulation (EU) 2017/745	Class IIa by Rule 10 of Annex VIII, Regulation (EU) 2017/745	Class IIa by Rule 11 of Annex VIII, Regulation (EU) 2017/745
MDA/MDN/MDT/MDS	MDA 0201, MDT 2010, MDT2011, MDS1009	MDA 0201, MDT 2010, MDT2011, MDS1009	MDA 0315, MDT2011, MDS1009
EMDN	Z11031180	Z11031180	Z11031182
GMDN	61108	61108	40866
Intended Use	Digital Imaging System detectors are digital flat panel detectors that is used for screening and diagnosis of disease or injury. These detectors are intended for use by a qualified/trained doctor or technician on subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts.		VXvue is intended to acquire Digital images from X-ray Detectors, process the images to facilitate diagnosis and to display, and transfer the resulting images to other devices for diagnostic purpose.

IV. Standard Compliance

Regulations and Technical Standards	Regulation (EU) 2017/745	EN ISO 13485:2016/A11:2021	EN ISO 14971:2019	EN 60601-1:2006/AC:2022-12	EN 60601-1-2 :2015/A1:2021	Directive 2011/65/EU
	EN 62304 :2006/A1 :2015	IEC 62304:2006/AMD1:2015	EN 62366-1:2015/A1:2020	EN 60601-1-6:2010/A2:2021	EN 62220-1-1 :2015	EC 1907/2006
Common Specifications	*N/A*					

V. The Conformity Assessment Procedure

Annex IX, (Chapter I) of Regulation (EU) 2017/745 on Medical Devices

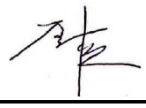
VI. MDR Compliance

We hereby declare that the product above is in conformity with Regulation (EU) 2017/745.
All supporting documentation is retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the declaration of conformity.

Digitally signed by Botnaru Andrei
Date: 2025.03.19 10:23:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Notified Body (2460)	DNV Product Assurance AS (Veritasveien 1, 1363 Høvik, Norway)
Certificate No.	C658257
Place, Date of issue	Anyang-si, Gyeonggi-do, Korea; 06 February, 2024
Valid Until	09 January, 2029

Signature



Hooshik Kim
President on behalf of Vieworks Co., Ltd.

Revision History

Rev	Date	Revision Contents
00	2024-02-06	First created
01	2024-04-09	Standard Compliance Added