

EC Certificate Full Quality Assurance System: Certificate BG19/871871

The management system of

VISARIS doo

Batajnički drum 10. deo 1b, 11080 Belgrade, Serbia

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Visaris Avanse family of digital x-ray diagnostic imaging systems
Visaris PACS (Picture Archiving and Communication system)
Diagon (Medical imaging diagnostic workstation)
Vision family of X-ray systems (ddRAura Series, ProXima Series)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 27 October 2020 until 17 August 2023
 and remains valid subject to satisfactory surveillance audits.
 Issue 3. Certified since 17 August 2006
 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BG/SOF 213593

Authorised by



SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Anexa 3 Sistem radiografic digital

Specificatia solicitata	Specificatia ofertata, model Vision V (Visaris/Serbia)
Descriere Sistem radiografic pentru uz general(oase, flurografie a pulmonilor etc) este utilizat pentru efectuarea procedurilor de rutina cu raze x pentru diagnostic Parametru Specificația Modul radiologic Digital Detector unic da Tip masă Tip Piedestal Suport electric da Mișcarea mesei Longitudinală, cm de la 80 Laterală, cm de la 20 Caracteristici Densitatea mesei <1 mm Al Dimensiunea minim 220 cm x 80 cm Înălțimea de la podea- fixaintre valorile 70-80 cm Miscarea mesa tip manuala Controlul mesei este prin intermediu comutatorul de picioare da Firina/ sistem de blocare tip electromagnetic Greutatea maximă a pacientului, kg de la 250 kg Spatiu pentru detector cm ≥35x43 Sistemul BUCKY a mesei Tip control manual Brat Orizontal complet controlabel da Mișcarea logitudionala a tubului ≥ 140 cm Mișcarea verticala a tubului ≥ 150 cm Punctul focal de la podea minim de la 40 pina la 190 cm Rotia tubului X-ray ≥ 180 ° (+ 90 °, 0 °, - 90 °) Sistem de blocareelectromagnetic BUCKY vertical Spatiu pentru detector cm ≥ 35x43 Punerea detectorului minim din dreapta si stinga Sistem de blocareelectromagnetic Deplasarea verticala, cm minim 150 cm (de la 40 -190 cm) Control Manual Detector Mărimea detector, cm ≥35x43 Configurare detector Rezoluția matricei, pixeli minim 1900x2000 Caracteristicile detectorului Distanța dintre pixel ≤ 175 μm Tip de ransmiter Wi-fi Funcția AED da Bloc / Sistem de incarcare separt fara cablu de interconectare da Scintilator / materialul de decție CsI Acumulator intern inclus tip Lithium Ion Tipul de lucru in regim AED ≥ 125 de expuneri Greutatea admisibila pe tota suprafata este de minim 300 kg conectarea Fără fir Wi-fi Generator de raze X Caracteristici Intensitatea maximă la 120 kV ≥ 50 kW Timpul de expunere in intrevalul minim 0.001-10 sec Intervalul mAs minim 0.1mAs-640mAs Tubul de raze X Dimensiunea spotului focal, mm 0.6 si 1.2 Voltajul anotic minim 150 kVp Rata de răcire, HU/min ≥ 300000 Panou de control pe tubul radiologic da Controlul razelor X a tubului montat da Spot focal mic ≤20 kW Spot focal mare ≥50 kW Colimator Tip obligatoriu LED	Descriere Sistem radiografic pentru uz general(oase, flurografie a pulmonilor etc) este utilizat pentru efectuarea procedurilor de rutina cu raze x pentru diagnostic Parametru Specificația Modul radiologic Digital Detector unic Tip masă Tip Piedestal Suport electric Mișcarea mesei Longitudinală, cm de la 80 Laterală, cm de la 20 Caracteristici Densitatea mesei <1 mm Al Dimensiunea 228 cm x 80,6 cm Înălțimea de la podea- fixaintre valorile 70-80 cm Miscarea mesa tip manuala Controlul mesei este prin intermediu comutatorul de picioare Firina/ sistem de blocare tip electromagnetic Greutatea maximă a pacientului, kg 300 kg Spatiu pentru detector cm 35x43 Sistemul BUCKY a mesei Tip control manual Brat Orizontal complet controlabel da Mișcarea logitudionala a tubului 250 cm Mișcarea verticala a tubului 153 cm Punctul focal de la podea minim de la 40 pina la 190 cm Rotia tubului X-ray ≥ 180 ° (+ 90 °, 0 °, - 90 °) Sistem de blocareelectromagnetic BUCKY vertical Spatiu pentru detector cm ≥ 35x43 Punerea detectorului minim din dreapta si stinga Sistem de blocareelectromagnetic Deplasarea verticala, cm 153 cm Control Manual Detector Mărimea detector, cm≥35x43 Configurare detector Rezoluția matricei, pixeli minim 1900x2000 Caracteristicile detectorului Distanța dintre pixel 139 μm Tip de ransmiter Wi-fi Funcția AED Bloc / Sistem de incarcare separt fara cablu de interconectare Scintilator / materialul de decție CsI Acumulator intern inclus tip Lithium Ion Tipul de lucru in regim AED ≥ 125 de expuneri Greutatea admisibila pe tota suprafata este de 300 kg conectarea Fără fir Wi-fi Generator de raze X Caracteristici Intensitatea maximă la 40-150 kV la 65 kW Timpul de expunere in intrevalul minim 0.001-10000 msec Intervalul mAs 0.1 – 1000 mAs Tubul de raze X Dimensiunea spotului focal, mm 0.6 si 1.2

Puterea ≥ 160 lx Fitrul 2.0 mm aluminiu Suspensia tubului Control razelor x a tubului montat da Statia de lucru Calculator Procesor minm I5 la 3,0 MHz Memorie RAM minim 4 GB HDD minim 320 GB HDD Sistem de operare minim Win 7 PRO Placa de reata Standartul RJ-45 minim 2 porturi Display tip LCD Multi-Touch DA Rezoluția minim 1920x1080 Diagonala ≥ 23 inch Soft de achizitie Implimentarea unei baze de pacienti (nume, prenume, anul de nastere sex etc) da Comunicarea cu date tip DICOM da Protocole de lucru preinstalte sa indice denumirea protocolleor de catre ofertant disponibile da Pozibilitatea de cautarea in baza de date dupa paramtri ca ID, Nume, Prenume etc. da Instrume de prelucrarea a imaginilor da Posibilitate de modificare a protocoalelor de lucru da Modul de iradier manual Automat Atomatizare in prelucarea imaginii da Posibilitatea de conectare minim 2 Printere DICOM minim 4 Statiti DICOM UPS Conform caracteristicilor electrice a calculatorului da Accesorii DAP metru inlcus da Cerințe față de alimentarea electrică Standard Prezenta inginerului calificat cu training de la producător pentru sisteme radiologice da Prezentarea graficului de venire a ingienrului pentru mententa in perioada de garantie da Certicate CE valabil da Declaratie de conformitate pentru produsul propus da Autorizatie de la producator pentru ofertant da	Voltajul anotic 150 kVp Rata de răcire, HU/min 300000 Panou de control pe tubul radiologic Controlul razelor X a tubului montat Spot focal mic ≤ 20 kW Spot focal mare ≥ 50 kW Colimator Tip obligatoriu LED Puterea ≥ 160 lx Fitrul 1.2 mm aluminiu Suspensia tubului Control razelor x a tubului montat Statia de lucru Calculator Procesor minm I5 la 3,0 MHz Memorie RAM minim 4 GB HDD minim 320 GB HDD Sistem de operare minim Win 7 PRO Placa de reata Standartul RJ-45 minim 2 porturi Display tip LCD Multi-Touch Rezoluția minim 1920x1080 Diagonala 23 inch Soft de achizitie Implimentarea unei baze de pacienti (nume, prenume, anul de nastere sex etc) Comunicarea cu date tip DICOM Protocole de lucru preinstalte sa indice denumirea protocolleor de catre ofertant disponibile Pozibilitatea de cautarea in baza de date dupa paramtri ca ID, Nume, Prenume etc. Instrume de prelucrarea a imaginilor Posibilitate de modificare a protocoalelor de lucru Modul de iradier manual Automat Atomatizare in prelucarea imaginii Posibilitatea de conectare minim 2 Printere DICOM minim 4 Statiti DICOM UPS Conform caracteristicilor electrice a calculatorului Accesorii: DAP metru inlcus Cerințe față de alimentarea electrică Standard Prezenta inginerului calificat cu training de la producător pentru sisteme radiologice Prezentarea graficului de venire a ingienrului pentru mententa in perioada de garantie Certicate CE valabil Declaratie de conformitate pentru produsul propus Autorizatie de la producator pentru ofertant
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Certificate BG06/67067

The management system of

VISARIS doo

Batajnički drum 10. deo 1b, 11080 Belgrade, Serbia

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design, manufacture and sales of diagnostic X-ray systems,
and medical imaging systems.**

This certificate is valid from 23 July 2020 until 17 August 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 August 2021
Issue 4. Certified since 12 January 2006

Authorised by

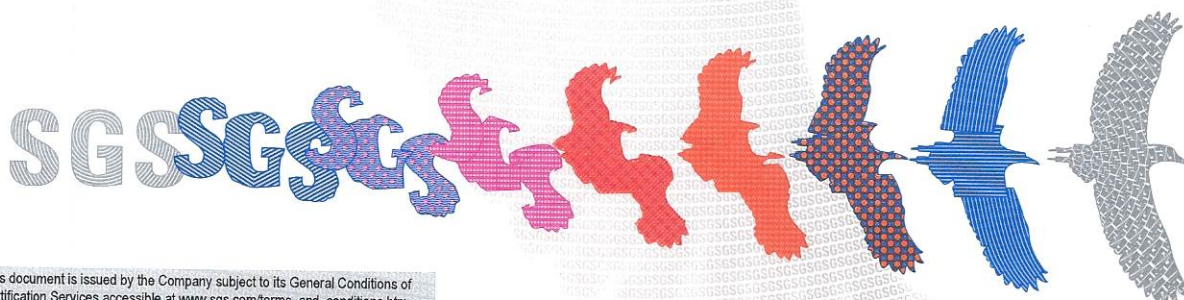
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TECHNICAL SPECIFICATION

Vision V – Floor Mounted Digital X-Ray System

Art. no: 1834007

VISION V – Digital Radiography System

VISION V is the universal digital X-ray system for general radiography. With a floor mounted tube stand (FMTS) and the digital flat panel detector it enables, in combination with a patient table it enables simple, comfortable and above all safe approach for both the patient and the technologist. It is used for all kinds of radiographic exams of the patients in lying, standing or sitting position, as well as for the exams of the patients on radiolucent hospital stretchers. By it's design and technical characteristics it complies with all the technical standards of accessibility also for persons with disabilities. Robust and simple design of the stand, combined with the „6-way“patient table, enables fast and easy positioning of the patient. The imaging process is extremelly simple and safe and is performed in fast and comfortable way.



VISION V

VISION V digital X-ray system is composed of following assemblies and components:

1. Patient table with bucky unit and AEC
2. Wall stand with bucky unit and AEC
3. Floor mounted tube stand (FMTS)
4. Generator
5. X-ray tube, collimator and DAP
6. Anti-scatter grids
7. Flat panel detector
8. Acquisition and imaging workstation

1. „6-way“ patient table



Patient table **VISION V**

Elevating patient table that is a part of **VISION V** system has a floating tabletop. Longitudinal and transversal movements. Available longitudinal and transversal movement of the tabletop enables fine corrections of patient position.

„6-way“ patient table – technical characteristics	
Patient table with floating tabletop	✓
Electromagnetic brakes for fixing the tabletop	✓
Bucky unit with removable anti-scatter grid	✓
Length of the tabletop	228 cm
Width of the tabletop	80,6 cm
Load capacity of the patient table	300 kg
Elevation range	30 cm
Elevation range from	52 cm
Longitudinal movement of the tabletop	±450 mm
Transversal movement of the tabletop	±125 mm
Motorized bucky movement range	50 cm
AEC, 5 field chamber	✓

2. Wall stand



Wall stand **VISION V**

Wall bucky stand of the **VISION V** system enables exams of the patients in standing position with varying height of the detector from the floor. Manual vertical movement from 280 to 1800 mm. Bucky unit containing removable grid and a wireless flat panel detector.

Wall stand with bucky unit – technical characteristics	
Fixation method	Fixed to the floor and to the wall
Vertical manual movement	28-180 cm
Bucky unit with removable anti-scatter grid	✓
Electromagnetic brake	✓
Patient handles for chest PA, LAT	✓
AEC, 5 field chamber	✓

3. Floor mounted tube stand (FMTS)

Floor mounted vertical stand for X-ray tube, moving along the rails. Manual movement, electromagnetic brakes for fixing in desired position.



Floor mounted tube stand VISION V

Technical characteristics of floor mounted tube stand	
Longitudinal movement of FMTS	2540 mm
Transversal movement of FMTS	250 mm
Vertical motorized/manual travel	1530mm
Rotation around vertical axis – mechanical indexation at every 90°	±180°
Rotation around horizontal axis – tube angulation	±135°
Electromagnetic brakes	✓
Tube side 10,1“ touchscreen console for control of system geometry, source-to-image distance display, exposition parameters (kV, mAs), AEC, APR selection and image preview	✓

4. Generator



High tension high frequency generator in **VISION V** system is software controlled, from the acquisition and imaging console. Generator complies with all the demands of radiography procedures. Technical characteristics of the generator are shown in the table below.

Technical characteristics of the generator, EMD RAD 65kW	
Generator power	65kW
Generator frequency	240 kHz
Exposure voltage range in 1 kV steps	40 – 150 kV
Exposure time	1-10.000ms
High speed starter	✓
Regulation range mA	10 – 800 mA
Regulation range mAs	0.1 – 1000 mAs
Selection of exposure anatomy programs (APR)	unlimited

5. X-ray tube, collimator and DAP



X-ray tube of the **VISION V** system is dimensioned so that there is no need for additional external cooling during the radiography procedures.

X-ray tube Varex Rad14/Leo	
Dual focus rotating anode	FI = 0.6mm and FII = 1.2mm

Anode heat capacity	300 kHU
Max. output voltage	150 kV
Tube assembly heat capacity	1.25 MHU
Manual beam collimator	Optica 20
Collimation control	Manual
Bucky Centering Light	Power LED white, adjustable luminosity
Rating	maximum 150 kVp
Collimator light luminance	160 lux
Inherent filtration, Al equivalent @ 75kV	1.2mm
DAP meter	IBA DAP KermaX Plus
DAP meter with generator interface and automatic readout in DICOM tag	✓
DAP integrated in the collimator	✓

6. Anti scatter grids

Two grids are delivered with the system with geometry that is corresponding to the values of SID for usual radiographic procedures:

1. Dense Anti-scatter grid Al, 10:1, f 110cm
2. Dense Anti-scatter grid Al, 10:1, f 180cm

7. Digital Flat Panel Detector



Digital flat panel detector iRay Mars 1717V3	
Receptor type	Amorphous silicium
Scintillator	CsI
DQE @ 0 lp/mm	66%
DQE @ 1 lp/mm	45%
Pixel pitch	139 μ m
Total image area	427 x 427 mm
Pixel matrix	3072 x 3072
A/D conversion	16 bit
Displaying of the image (preview/full image)	3s/5s
Detector type	Portable, highly sensitive
Communication	Wireless, Wifi
Detector weight (with battery)	4.6 kg
Ingress protection	IPX1
Weight capacity (distributed)	150 kg
Set containing two batteries and a battery charger	✓

8. Avanse DR Acquisition and Imaging System

Acquisition and imaging workstation **Visaris Avanse DR** is the integral component of the **VISION V** system. It is designed for centralized control of the digital radiography system. It is the control center from which the generator (exposure control, selection of anatomy program) and acquisition and imaging system (patient data, worklist import, image post-processing and DICOM operations) are controlled.



Acquisition and imaging workstation

Patient imaging is performed in extremely simple way, maximally adjusted to the needs of an x-ray technologist. User interface is in customer's language. Five essential steps in workflow are:

1. Selection of patient
2. Selection of projections
3. Exposure
4. Image processing
5. Image export and publishing

DICOM Modality Worklist integration

Beside the usual way of direct input of patient data the acquisition system supports the import of modality worklists (MWL) in DICOM format from the supported MWL or PACS servers. User interface enables simple query of created MWLs by patient or modality details and their direct import in workflow.

Image processing

The system offers extraordinary post processing features for visualization of region of interest (screenshot shown in following image). Some of the basic image processing tools are:

- Histogram (selection of grayscale range for the best view of ROI);
- Horizontal and vertical image flipping;
- Zoom in or zoom out;
- Cropping of ROI;
- Measurements of distances;
- Positive, negative view;
- Exposure index display for every image;
- Magnification of details;
- Image archiving on PACS server in DICOM format etc.



Image processing

Software for optimization of image quality

Beside the usual tools for image processing, Avanse DR acquisition console provides a number of specialized advanced techniques of image post-processing. Visaris β (Beta) algorithm enables normalization and harmonization of response of grayscale for wide range of exposure parameters thus enabling a way increased sensitivity compared to conventional and CR systems. That way the acceptable image quality, contrast and brightness is achieved in underexposed and overexposed regions. By this multi-frequency processing of X-ray image the structure of bones and soft tissue is enhanced. Predefined parameters of image processing are changeable and the chosen values can be saved.

Printing, archiving and making annotations

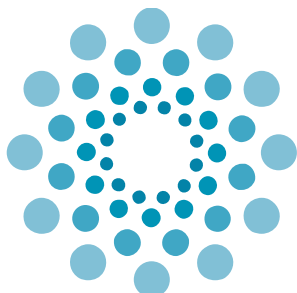
The printing module of processed images enables selection of printing media (paper or film), format of media, selection of desired display of rows and columns, and printing of images with annotations showing patient and anatomy details, orientation, exposure parameters etc.

CD/DVD Publishing

Avanse DR acquisition and imaging system enables direct archival of obtained images on CD/DVD media in DICOM format with all the parameters of the exam performed. With every study recorded to the CD/DVD media the free DICOM viewer is enclosed, which automatically runs when the CD/DVD is inserted in any PC computer and the recorded images are displayed.

Avanse DR acquisition and imaging workstation	
High performance PC, multi core processor, min. i5	✓
RAM	8 GB
Hard disk drive 500 GB, with capacity of more than 15.000 images	1 TB
Display size	23"

Display resolution	Full HD
DVD RW for export of images in DICOM format	✓
Operating system	Windows
DICOM 3.0 MWL SCU import of modality worklists	✓
DICOM 3.0 Store SCU export to PACS	✓
DICOM 3.0 Print SCU print to DICOM printer	✓
DICOM 3.0 Query, Retrieve, MPPS, Storage commitment	
Tools for image processing: zoom, contrast, brightness, rotate, flip, inverse, magnification	✓
Algorithm for automatic harmonization	✓
Advanced tools for image processing with enhanced visualization of bones and soft tissues	✓
Integration with PACS and RIS enabled	✓
Image printing on paper or film	✓
Image archival and export in DICOM format	✓
Image publishing on CD/DVD media in DICOM format with free DICOM viewer	✓
Annotation tools	✓
Dose SR	✓



V I S A R I S



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