

# Anexa nr. 1 la Formularul Specificații tehnice Anexa 22

## Tomograf Computerizat Ortopedic

### model **Planmed Verity**

| SPECIFICATII TEHNICE SOLICITATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | SPECIFICAȚII TEHNICE OFERTATE: <b>model Planmed Verity, producator Planmed Oy, Finlanda</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
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| <p>Tomograf Computerizat Ortopedic</p> <p>Caracteristici generale:</p> <p>Sistem de radiografie necesar pentru imagistica ortopedică, precum și pentru scanare cap și gât.<br/> Dispozitivul sa prezinte o dimensiune compacta, usor de amplasat.<br/> Dispozitivul sa dispuna de soft care va permite reglarea dozei de radiatie<br/> Dispozitivul sa dispuna de soft care va permite corectarea artefactelor de mișcare.</p> <p><b>CARACTERISTICI TEHNICE TUB X-RAY:</b><br/> Tub cu raze X cu țintă de tungsten<br/> Dimensiunea spotului focal <math>\geq 0,6</math> mm<br/> Tensiune anodică: <math>\leq 100</math> kV<br/> Curentul anodic: <math>\leq 15</math> mA<br/> Filtrare dublă: 0,5 mm Cu + 2,5 mm Al<br/> Radiații cu raze X pulsate, care va minimiza doza de radiatie pentru pacient</p> <p><b>CARACTERISTICI TEHNICE DETECTOR:</b><br/> Detector tip Flat panel (integrat)<br/> Dimensiune detector: 20 x 25 cm (siliciu amorf) (<math>\pm 5</math> cm)<br/> Interval dynamic: 16 biți<br/> Timp scanare in 3D (s): de la 10-30 sec.<br/> Dimensiune pixeli: <math>\leq 127</math> um<br/> Dimensiune matrice de <math>\geq 1.536 \times 1.920</math> pixeli</p> <p><b>CARACTERISTICI TEHNICE IMAGE DE ACHIZITIE:</b><br/> Sistemul sa permita achizitia de imagini prin modurile: Doză ultra mică, Standard și Rezoluție înaltă<br/> Sistemul sa permita previzualizarea imaginii inainte de expunerea pacientului<br/> Controlul automat al expunerii (AEC)<br/> Câmp vizual: 13 x 16 cm cu o singură scanare<br/> Sistemul sa permita achitionarea de 300-600 imagini de proiecție (configurabile) intr-un diapazon de la 0 - 200 grade<br/> Timp de expunere: nu mai mult 7 sec., pulsats,<br/> Timp de reconstrucție: 30-120sec., în dependenta de modul de imagistica</p> <p><b>CARACTERISTICI TEHNICE SISTEM DE ACHIZITIE SI RECONSTRUCTIE:</b><br/> Sistemul de radiografie sa fie livrat cu un sistem de achizitie si reconstrucie</p> | <p>Tomograf Computerizat Ortopedic</p> <p>Caracteristici generale:</p> <p>Sistem de radiografie necesar pentru imagistica ortopedică, precum și pentru scanare cap și gât.<br/> Dispozitivul prezinta o dimensiune compacta, usor de amplasat.<br/> Dispozitivul dispune de soft care va permite reglarea dozei de radiatie<br/> Dispozitivul dispune de soft care va permite corectarea artefactelor de mișcare.</p> <p><b>CARACTERISTICI TEHNICE TUB X-RAY:</b><br/> Tub cu raze X cu țintă de tungsten<br/> Dimensiunea spotului focal de 0.6mm<br/> Tensiune anodică: 80-96kV<br/> Curentul anodic: 1-12mA<br/> Filtrare dublă: 0,5 mm Cu + 2,5 mm Al<br/> Radiații cu raze X pulsate, care va minimiza doza de radiatie pentru pacient</p> <p><b>CARACTERISTICI TEHNICE DETECTOR:</b><br/> Detector tip Flat panel (integrat)<br/> Dimensiune detector: 20 x 25 cm (siliciu amorf)<br/> Interval dinamic: 16 biți<br/> Timp scanare in 3D (s): 18 sec.<br/> Dimensiune pixeli: 127 um<br/> Dimensiune matrice de 1.536 x 1.920 pixeli</p> <p><b>CARACTERISTICI TEHNICE IMAGE DE ACHIZITIE:</b><br/> Sistemul sa permita achizitia de imagini prin modurile: Doză ultra mică, Standard și Rezoluție înaltă<br/> Sistemul sa permita previzualizarea imaginii inainte de expunerea pacientului<br/> Controlul automat al expunerii (AEC)<br/> Câmp vizual: 13 x 16 cm cu o singură scanare, prin fuziune până la 16 x 20 cm<br/> Sistemul permite achitionarea de 300-600 imagini de proiecție (configurabile) la un unghiul de 210 grade<br/> Timp de expunere: 6 sec., pulsats,<br/> Timp de reconstrucție: 30-120sec., în dependenta de modul de imagistica</p> <p><b>CARACTERISTICI TEHNICE SISTEM DE ACHIZITIE SI RECONSTRUCTIE:</b> <i>Planmed Verity Workstation PC &amp; Eizo RadiForce MX315W &amp; Romexis 3DAdvance Licence:</i><br/> Sistemul de radiografie va fi livrat cu un sistem de achizitie si reconstrucie</p> |

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| <p>Sistemul sa fie livrat cu hard disk-uri duale configurate Raid 1 (1000 GB) pentru fiabilitate și performanță îmbunătățită. Reconstrucție accelerată rapidă a GPU-ului.</p> <p><b>CARACTERISTICI TEHNICE GANTRY:</b><br/> Mișcarea motorizată în sus/jos/inclinare, ca va garanta poziționarea optima pentru pacient.<br/> Interval de mișcare a înălțimii de la podea: <math>\geq 55-110</math> cm<br/> Intervalul de mișcare a înclinării <math>+15^{\circ}/-90^{\circ}</math><br/> Poziția de gantry orizontală<br/> Apertura cu un diametru de minim 40 cm<br/> Sa dispuna de sensori care vor recunoaste tinte, fapt care va impiedica mișcări automate ale gantry-lui, atunci când pacientul este poziționat în interior.</p> <p>Sistemul sa dispuna de mecanism de poziționare motorizat a pacientului care va centra ținta în câmpul vizual.</p> <p>Sistemul sa fie configurat cu 2 (doua) joystick-uri pentru mișcările controlate ale gantry-lui, a sistemului de poziționare și a colimatorului.</p> <p>Dispozitivul sa dispuna de lumini pentru ghidare pozitionare.</p> <p>Interfață utilizator, ecran tactil<br/> - cu înălțime si inclinare reglabilă<br/> - sa poata fi utilizat cu sau fara manusi</p> <p><b>CARACTERISTICI TEHNICE SOFTWARE:</b><br/> Achiziție intuitivă, optimizată pentru ecran tactil și software de comunicare<br/> Informații despre pacient și instrumente de bază de date<br/> Procedura bazată pe anatomie și selecția țintei.<br/> Selectarea dimensiunii pacientului kV, mAs, afișare a dozei<br/> Crearea unui protocol de imagistică definit de utilizator<br/> Interfață de acționare prestabilă pentru portal automat și mișcări ale sistemului de poziționare cu parametri prestabiliți definibili de utilizator<br/> Afișarea imaginii Scout<br/> Instrumente de procesare și adnotare a imaginilor pentru generarea și revizuirea reconstrucțiilor multiplanare și a randărilor 3D<br/> Instrument de tăiere pentru a genera stive de date pentru arhivare<br/> Modul service cu instrumente QA integrate<br/> DICOM 3.0<br/> Reconstituirea imaginii cu parametri selectabili<br/> Algoritm de suprimare a metalelor<br/> Nuclee de reconstrucție selectabile de utilizator<br/> Algoritm de filtrare a zgomotului<br/> Algoritm corectarea artefactelor de mișcare<br/> Protocol de imagistic</p> <p>Aplicatii de soft pentru imagistica cap și gât<br/> Imagini extinse cu pachet care vor include suport pentru cap și gât, actualizare software și licență<br/> Sa dispuna de suport rigid pentru cap pentru o calitate maximă a imaginii.</p> | <p>Sistemul sa fie livrat cu hard disk-uri duale configurate Raid 1 (1000 GB) pentru fiabilitate și performanță îmbunătățită. Reconstrucție accelerată rapidă a GPU-ului.</p> <p><b>CARACTERISTICI TEHNICE GANTRY:</b><br/> Mișcarea motorizată în sus/jos/inclinare, ca va garanta poziționarea optima pentru pacient.<br/> Interval de mișcare a înălțimii de la podea: 55-112 cm<br/> Interval de mișcare a înclinării <math>+15^{\circ}/-90^{\circ}</math><br/> Poziția de gantry orizontală<br/> Apertura cu un diametru de 40 cm<br/> Dispune de sensori care vor recunoaste tinte, fapt care va impiedica mișcări automate ale gantry-lui, atunci când pacientul este poziționat în interior.</p> <p>Sistemul dispune de mecanism de poziționare motorizat a pacientului care va centra ținta în câmpul vizual.</p> <p>Sistemul este configurat cu 2 (doua) joystick-uri pentru mișcările controlate ale gantry-lui, a sistemului de poziționare și a colimatorului.</p> <p>Dispozitivul dispune de lumini pentru ghidare pozitionare.</p> <p>Interfață utilizator, ecran tactil<br/> - cu înălțime si inclinare reglabilă<br/> - sa poata fi utilizat cu sau fara manusi</p> <p><b>CARACTERISTICI TEHNICE SOFTWARE:</b><br/> Achiziție intuitivă, optimizată pentru ecran tactil și software de comunicare<br/> Informații despre pacient și instrumente de bază de date<br/> Procedura bazată pe anatomie și selecția țintei.<br/> Selectarea dimensiunii pacientului kV, mAs, afișare a dozei<br/> Crearea unui protocol de imagistică definit de utilizator<br/> Interfață de acționare prestabilă pentru portal automat și mișcări ale sistemului de poziționare cu parametri prestabiliți definibili de utilizator<br/> Afișarea imaginii Scout<br/> Instrumente de procesare și adnotare a imaginilor pentru generarea și revizuirea reconstrucțiilor multiplanare și a randărilor 3D<br/> Instrument de tăiere pentru a genera stive de date pentru arhivare<br/> Modul service cu instrumente QA integrate<br/> DICOM 3.0<br/> Reconstituirea imaginii cu parametri selectabili<br/> Algoritm de suprimare a metalelor<br/> Nuclee de reconstrucție selectabile de utilizator<br/> Algoritm de filtrare a zgomotului<br/> Algoritm corectarea artefactelor de mișcare<br/> Protocol de imagistică</p> <p>Aplicatii de soft pentru imagistica cap și gât<br/> Imagini extinse cu pachet care vor include suport pentru cap și gât, actualizare software și licență<br/> Dispune de suport rigid pentru cap pentru o calitate maximă a imaginii.</p> |
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| <p>Dimensiuni: 80x190x170cm, <math>\pm 50</math> cm<br/> Greutate: nu mai mult de 450 kg<br/> Baza mobila selectabila cu roti sau baza fixa, de sine statatoare<br/> Mâner multifuncțional pentru pacient și pentru deplasarea unității în poziția de transport<br/> Dispozitivul sa nu necesite răcire externă<br/> Dispozitivul sa se conecteze la o priză electrică standard</p> <p>Dispozitivul sa fie livrat cu urmatoarele accesorii:<br/> Suport poziționare, cu atenuare redusă, fabricate din fibră de carbon<br/> Suport poziționare a zonei mici, mari și plane<br/> Suport poziționare vertical, reglabilă.<br/> Scaun dedicat pentru poziționarea pacientului, cu maner si roti blocabile.</p> | <p>Dimensiuni: 76x184x160cm,<br/> Greutate: 350 kg<br/> Baza mobila selectabila cu roti sau baza fixa, de sine statatoare<br/> Mâner multifuncțional pentru pacient și pentru deplasarea unității în poziția de transport - da<br/> Dispozitivul nu necesite răcire externă<br/> Dispozitivul se conecteaza la o priză electrică standard.</p> <p>Dispozitivul va fi livrat cu urmatoarele accesorii, <i>Patient Positioning Trays</i>:<br/> Suport poziționare, cu atenuare redusă, fabricate din fibră de carbon - da<br/> Suport poziționare a zonei mici, mari și plane - da<br/> Suport poziționare vertical, reglabilă - da<br/> Scaun dedicat pentru poziționarea pacientului, cu maner si roti blocabile, model <i>MYS-1050N PATIENT TRANSFER CHAIR</i>.</p> |
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Natalia Chicu

Administrator "Intermed" SRL

# REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

| Nr          | Denumire                                              | Den.comerc.         | Model                | Nr. catalog | Tara     | Producatorul | Reprezentant    | Ordin       | Data       |
|-------------|-------------------------------------------------------|---------------------|----------------------|-------------|----------|--------------|-----------------|-------------|------------|
|             |                                                       |                     | C                    |             |          | Planmed      |                 |             |            |
| DM000366947 | TOMOGRAF<br>COMPUTERIZAT CU<br>CÂMP VIZUAL<br>LIMITAT | PLANMED<br>VERITY®  | EXTREMITY<br>SCANNER |             | Finlanda | PLANMED OY   | INTERMED S.R.L. | Rg04-000196 | 18-07-2022 |
| DM000366946 | MAMOGRAF<br>DIGITAL                                   | PLANMED<br>CLARITY™ | CU RAZE X            |             | Finlanda | PLANMED OY   | INTERMED S.R.L. | Rg04-000196 | 18-07-2022 |

## Attachment 1, issue 2 to SGS Fimko Ltd. EC certificate FI15/07007, issue 2

|                                                     |                                                                                         |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                                 | Planmed Oy                                                                              |
| <b>Address</b>                                      | Sorvaajankatu 7, 00880 Helsinki, Finland                                                |
| <b>Activity and Medical Device Product Category</b> | 93/42/EEC Annex II (excluding Section 4)<br>Diagnostic X-ray equipment and accessories. |

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

| <b>Medical Device</b>                       | <b>Class</b> | <b>Trademark(s) and Model(s)/type(s)</b> |
|---------------------------------------------|--------------|------------------------------------------|
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Clarity                          |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Nuance Excel                     |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Nuance Classic                   |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Nuance                           |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Sophie Classic                   |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Sophie Classic S                 |
| Mammography x-ray unit, GMDN 37672, MD 1201 | IIb          | Planmed Sophie                           |
| X-ray unit, GMDN 37619, MD 1201             | IIb          | Planmed Verity                           |
| Stereotactic accessories MD 1109            | IIa          | Planmed DigiGuide                        |
| Stereotactic accessories MD 1109            | IIa          | Planmed Nuance DigiGuide                 |

Authorised by



Seppo Vahasalo, Notified Body Manager  
SGS Fimko Ltd., Notified Body 0598

Date issued/revised: 7 January 2019  
This certification is based on decision: FI18/07016P0



EC Certificate Full Quality Assurance System FI15/07007

The management system of

# Planmed Oy

Planmed Oy  
Sorvaajankatu 7  
00880 Helsinki  
Finland

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  
**Diagnostic X-ray equipment and accessories**

Products covered are listed in Attachment 1 of this certificate

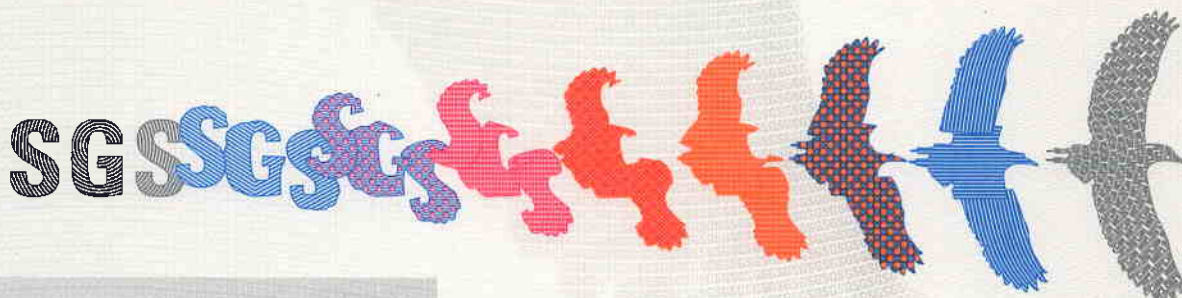
This certificate is valid from 7 January 2019 until 8 October 2023  
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 8 October 2010  
This certification is based on decision: FI18/07016P0

Authorised by



Seppo Vahasalo, Notified Body Manager  
SGS Fimko Ltd., Notified Body 0598



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
62008-2009-AQ-FIN-FINAS

Initial certification date:  
01 January 1995

Valid:  
01 November 2021 – 31 October 2024

This is to certify that the management system of

**Planmed Oy**

Sorvaajankatu 7, 00880 Helsinki, Finland

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

**ISO 9001:2015**

This certificate is valid for the following scope:

**Development, manufacture, marketing, sales and after sales of mammography X-ray equipment, medical X-ray equipment, software and their accessories.**

Place and date:  
Espoo, 27 October 2021

For the issuing office:  
**DNV - Business Assurance**  
Keilaranta 1, 02150 Espoo, Finland



**Kimmo Haarala**  
Management Representative

## Appendix to Certificate

### Planmed Oy

Locations included in the certification are as follows:

| Site Name                     | Site Address                                       | Site Scope                                                                                                                                          |
|-------------------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Planmed Oy                    | Sorvaajankatu 7, 00880 Helsinki, Finland           | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |
| Planmed Oy (Asentajankatu)    | Asentajankatu 6, 00880 Helsinki, Finland           | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |
| Planmed Oy (Lähetämö/varasto) | Teollisuusneuvoksenkatu 3, 00880 Helsinki, Finland | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
10000475805-MSC-FINAS-FIN

Initial certification date:  
01 January 1995

Valid:  
01 November 2021 – 31 October 2024

This is to certify that the management system of

**Planmed Oy**

Sorvaajankatu 7, 00880 Helsinki, Finland

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

**ISO 13485:2016**

This certificate is valid for the following scope:

**Development, manufacture, marketing, sales and after sales of mammography X-ray equipment, medical X-ray equipment, software and their accessories.**

Place and date:  
Espoo, 27 October 2021

For the issuing office:  
**DNV - Business Assurance**  
Keilaranta 1, 02150 Espoo, Finland



**Kimmo Haarala**  
Management Representative

## Appendix to Certificate

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| Planmed Oy                    | Sorvaajankatu 7, 00880 Helsinki, Finland           | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |
| Planmed Oy (Asentajankatu)    | Asentajankatu 6, 00880 Helsinki, Finland           | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |
| Planmed Oy (Lähetämö/varasto) | Teollisuusneuvoksenkatu 3, 00880 Helsinki, Finland | Development, manufacture, marketing, sales and after sales of mammography x-ray equipment, medical x-ray equipment, software and their accessories. |

# Planmed

## Technical Training

Certificate of attendance

**Alexei Legun**

from Intermed SRL

has participated in

**Planmed Technical Training** covering the following products:  
**Planmed Verity**

at Helsinki

on 10 - 12 December 2019.



Mikko Viitanen  
Technical Product Specialist, After Sales  
Planmed Oy

# Planned Verity Review Workstation

## Workstation Specifications

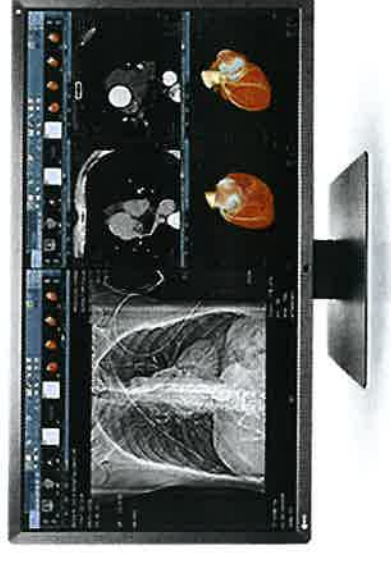
### Review Workstation Computer

- Dell T5820
- Intel Xeon W-2104 (3.2GHz)
- RAM 32 GB (8x4GB) 2400MHz
- NVIDIA Quadro P2000 5 GB
- Dual, 1 TB hard drives in RAID 1
- DVD recorder
- Keyboard/mouse
- Microsoft Windows 10 operating system
- 10/100/1000 Base T Ethernet



### Optional Precision Monitor

- Eizo RadiForce MX315W 8MP
- Size 31.1" / 79 cm
- Native Resolution 4096 x 2160 (17:9)
- DVI-D (dual link) x 1, DisplayPort x 2
- <https://www.eizo.com/products/radiforce/mx315w/>



*Evolve Your Image Reading*

**Planned**

# Planmed Verity®

## Key Facts

- Unique CBCT scanner for orthopedic as well as head and neck imaging
- Exceptional image quality
- Versatile tool for imaging centers and hospitals
- Compact size, easy to site
- Weight-bearing imaging
- Planmeca Ultra Low Dose™
- Movement artefact correction with Planmeca CALM™

## X-Ray Tube

- Canon X-ray tube with tungsten target and 0.6mm focal spot size
- Anode voltage: 80-96kV
- Anode current: 1-12mA
- Dual filtration: 0.5mm Cu + 2.5mm Al
- Pulsed X-ray radiation minimizes dose for the patient

## Flat Panel Detector

- 20 x 25cm flat panel detector (amorphous silicon)
- 16bit dynamic range
- High speed image acquisition with up to 30fps
- Pixel size: 127µm
- 1,536 x 1,920 pixel matrix

## Image Acquisition

- Three imaging modes: Ultra low dose, Standard and High resolution
- Scout image
- Automatic Exposure Control (AEC)
- Field of View: 13 x 16 cm with single scan, stitched up to 16 x 20cm
- Isotropic resolution: up to 0.2mm
- 300-600 (configurable) projection images acquired over an angle of 210 degrees
- Scan time: 18 seconds (with default settings)
- Exposure time: Pulsed, 6s (effective with default settings)
- Reconstruction time of 30-120s depending on the imaging mode

## Integrated Acquisition and Reconstruction PC

- Integrated, high performance acquisition and reconstruction computer
- Raid 1 (mirror) configured dual hard drives (1000GB) for improved reliability and performance
- Fast GPU accelerated reconstruction

## Adaptable Gantry

- Motorized up/down/tilt movement guarantees optimal positioning for the patient
- Height movement range 55-112cm from the floor
- Tilt movement range +15°/-90°
- Horizontal gantry position for optional weight-bearing CBCT
- Soft upholstery for comfortable imaging experience
- Unique, configurable upholstery colors: Lilac, Dark Blue, Mint, Sahara Yellow, Lime, Fuchsia, Graphite

## TearDrop™ Shaped Bore

- Maximized bore with diameter of 40cm optimizes the space available for patient positioning
- Target recognition function prevents automatic gantry movements when the patient is positioned inside the bore
- Field of view highlighted by red and green lasers

## Precision Patient Positioning

- Motorized patient positioning mechanism that centers the target in the field of view
- Target specific carbon fibre positioning trays for optimal patient positioning
- Optional weight-bearing imaging accessories
- HoverTray™ patient positioning mode for maximal patient comfort

## Intelligent Joysticks

- Two joysticks for controlled movements of the gantry, positioning system and collimator
- Located at the gantry and next to the touch screen
- Optimized for intuitive use while positioning the patient
- Blue indicator lights to guide

## Touch Screen User Interface

- Height adjustable and tilting touch screen interface
- Can be operated with or without gloves



## Verity Manager Software

- Intuitive, touch-screen optimized image acquisition and communication software
- Patient information and database tools
- Anatomy-based procedure and target selection
- Patient size selection
- kV, mAs, dose display
- User definable imaging protocol creation
- Pre-set drive interface for automatic gantry and positioning system movements with user definable pre-set parameters
- Scout image display
- Image processing and annotation tools for generation and review of multi-planar reconstructions and 3D renderings
- Slicing tool to generate stacks of data for archiving
- Service mode with integrated QA tools
- DICOM 3.0 conformant
- Image reconstruction with selectable parameters
- Metal suppression algorithm
- User selectable reconstruction kernels
- Noise filtering algorithm
- Planmeca CALM™ movement artefact correction algorithm
- Planmeca Ultra Low Dose™ imaging protocol

## General Information

- Dimensions (WxLxH): 76x184x160cm
- Weight 350kg
- Selectable mobile base with wheels or fixed, freestanding base
- Multipurpose handle for the patient and for moving the unit when in transport position
- Fits through standard doors
- No need for external cooling
- Plugs into a standard electric outlet

## Optional features and accessories

### **Patient Positioning Trays**

- *Light-weight, low attenuation positioning trays manufactured from carbon fiber*
- *Small, large, and flat area positioning tray*
- *Adjustable vertical positioning tray*

### **Weight-Bearing Option**

- *Dedicated weight-bearing carbon fiber stool with adapter*
- *Additional retractable support handle in the vertical column for the patient*
- *Software support for weight-bearing imaging*

### **Maxillofacial Imaging Option**

- *Extended imaging with optional package that includes maxillofacial*
- *support tray, software update and license key*
- *Open design with seated positioning and easy adjustments*
- *Add-on feature to all Planmed Verity units*

### **Head and Neck Imaging Option**

- *Extended imaging with optional package that includes head and neck support tray, software update and license key*
- *Rigid head support for maximal image quality*
- *Add-on feature to all Planmed Verity units*

### **Dedicated Chair**

- *Dedicated patient positioning chair*
- *Handle for adjusting the chair*
- *Lockable wheels*
- *Configurable upholstery color that matches the unit*

### **Planmeca Romexis® 3D**

- *Image review workstation based on Planmeca Romexis®*

## MYS-1050N

PATIENT TRANSFER CHAIR

FAUTEUIL DE TRANSFERT DE PATIENT



### DIMENSIONS

#### Chair Position:

|                        |          |
|------------------------|----------|
| Width / Largeur (cm)   | 50 (cm)  |
| Length (cm) / Longueur | 44 (cm)  |
| Height / Hauteur (cm)  | 128 (cm) |

#### Stretcher Position:

|                        |          |
|------------------------|----------|
| Width / Largeur (cm)   | 50 (cm)  |
| Length (cm) / Longueur | 185 (cm) |
| Height / Hauteur (cm)  | 59 (cm)  |



### GENERAL SPECIFICATIONS

- Backrest adjusted by gas-spring
- Foot part can be moved alone or with backside together
- Telescopic IV pole
- Armrest with height adjustment
- It becomes stretcher in emergency
- Electrostatic powder coated metallic chassis

### CARACTÉRISTIQUES TECHNIQUES

- Dossier ajustable avec ressort à gaz
- Partie inférieure déplaçable seule ou avec le dossier
- Potence télescopique
- Accoudoir réglable en hauteur
- Utilisation en brancard en cas d'urgence
- Châssis métallique à peinture électrostatique

## MYS-1050P

STACKABLE PATIENT TRANSPORT CHAIR

FAUTEUIL DE TRANSPORT PATIENT EMPILABLE



### DIMENSIONS

|                                   |
|-----------------------------------|
| Width (armrest to armrest: 570mm) |
| Total Height: 1020 mm             |
| Total Width: 695 mm               |
| Total Length: 890 mm              |



### GENERAL SPECIFICATIONS

- Stainless Steel Profile main frame
- Push handle and foot support
- Brake release handle
- Top quality PU based rear and front wheels (200 x 500 mm rear, 152 x 32 front)
- %68 space saving when stackable
- Foldable armrest and footrest

### CARACTÉRISTIQUES TECHNIQUES

- Profilé du Châssis en Acier inoxydable
- Poignée de poussée et repose-pieds
- Poignée de desserrage des freins en acier inoxydable
- Roues arrière et avant à base de PU de qualité supérieure (arrière 200 x 500 mm, avant 152 x 32)
- Economie de 68% d'espace lors du jalonnement
- Accoudoir et repose-pieds pliables



## EC DECLARATION OF CONFORMITY AB UYGUNLUK BEYANI

**Manufacturer/İmalatçı:** MEYOSİS HASTANE EKİPMANLARI SAN. VE TİC. A.Ş.

İnönü Mah. Kayışdağı Cad. No:128/1 Kandış İ.M.- Ataşehir, İstanbul, TURKEY / TÜRKİYE

Tel: (+90) 216 574 67 38 info@meyosis.com www.meyosis.com

**Factory/Fabrika:** 75. Yıl Caddesi No:110/2 Hadımköy, İstanbul, TURKEY / TÜRKİYE

**Product Scope / Ürün Kapsamı:** HOSPITAL EQUIPMENT / HASTANE EKİPMANLARI

**Products / Ürünler:** It is listed in the appendix of this document / Bu belgenin ekinde listelenmiştir

This declaration of conformity is issued under the sole responsibility of Manufacturer. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) **MDR 2017/745** for medical devices. This declaration is supported by the Quality System approval ISO 13485. All supporting documentation is retained at the premises of the manufacturer. /

*Bu uygunluk beyanı, tamamen Üreticinin sorumluluğunda yayınlanmıştır. Yukarıda belirtilen tıbbi cihaz(lar)ın tıbbi cihazlara ilişkin (AB) MDR 2017/745 tüzüğüne hükümlerini karşıladığını beyan ederiz. Bu beyan, Kalite Sistem onayı ISO 13485 tarafından desteklenmektedir. Tüm destekleyici belgeler, üreticinin tesislerinde muhafaza edilmektedir.*

| Conformity assessment route/<br>Uygunluk değerlendirme rotası. | Classification/Sınıflandırma:                                                                     |
|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Annex IV (Annex II & III) /<br>Ek IV (Ek II & III)             | Class I product according to Rule 1 of Annex VIII /<br>Ek VIII Kural 1'e göre <b>Sınıf I</b> ürün |

**Standarts/Standartlar:**

EN ISO 14971, EN ISO 9001, EN ISO 13485, EN ISO 15223-1, EN 60601-2-52, EN 60601-1, EN 60601-2-38

### ON BEHALF OF MANUFACTURER / ÜRETİCİ ADINA

**Name/Adı:** Mehmet Öğün GEYİK (imza yetkisi- authorized signatory)

**Date-Place/Tarih-Yer :** 07.12.2021 / İstanbul

**Signature/İmza:**



MEYOSİS HASTANE EKİPMANLARI  
SAN. VE TİC. A.Ş.  
İnönü Mah. Kayışdağı Cad. No:128  
K:1 Kandış İl. Merkezi Ataşehir İST.  
Kozyatağı V.D. 742 046 2891  
Tic. Sic. No 44513-5



## Products list / Ürün listesi

| Basic/Temel<br>UDI | Product name/<br>Ürün adı                                                           | REF                                                                                                                                                                            | GMDN  |
|--------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| 86817195AMLYATYC   | OPERATING THEATER<br>TABLE/ <i>AMELİYAT<br/>MASASI</i>                              | MYS-STG                                                                                                                                                                        | 38149 |
| 86817195DOGJINX7   | DELIVERY CHAIR/ <i>DOĞUM<br/>YATAĞI</i>                                             | MYS-923, MYS-723                                                                                                                                                               | 15732 |
|                    | GYNECOLOGIC<br>EXAMINATION COUCH/<br><i>JİNEKOLOJİK MUAYENE<br/>YATAĞI</i>          | MYS-724,                                                                                                                                                                       | 36065 |
| 86817195KOLTUK5Q   | BLOOD DONOR CHAIR/<br><i>KAN ALMA KOLTUĞU</i>                                       | MYS-718, MYS-818                                                                                                                                                               | 10789 |
|                    | PATIENT TRANSFER<br>CHAIR/ <i>HASTA TRANSFER<br/>KOLTUĞU</i>                        | MYS-1050N                                                                                                                                                                      | 31163 |
|                    | CHEMOTHERAPY AND<br>SKIN CARE CHAIR/<br><i>KEMOTERAPİ VE CİLT<br/>BAKIM KOLTUĞU</i> | MYS-931                                                                                                                                                                        | 38447 |
| 86817195KRYOLA2DN  | 2 MOTORS HOSPITAL BED/<br><i>İKİ MOTORLU HASTA<br/>KARYOLASI</i>                    | MYS-5210NE, MYS-5200B,<br>MYS-5200BN, MYS-5210N                                                                                                                                | 34870 |
|                    | 2 MOTORS PEDIATRIC<br>HOSPITAL BED/ <i>İKİ<br/>MOTORLU PEDIYATRİK<br/>KARYOLA</i>   | MS-513MN, MYS-520N,<br>MYS-550P                                                                                                                                                | 37010 |
| 86817195KRYOLA3DQ  | 3 MOTORS HOSPITAL BED/<br><i>ÜÇ MOTORLU HASTA<br/>KARYOLASI</i>                     | MYS-5320NE, MYS-5310B,<br>MYS-5320N, MYS-5320Y,<br>MYS-5330N, MYS-5330NE,<br>MYS-5330Y                                                                                         | 34870 |
|                    | 3 MOTORS PEDIATRIC<br>HOSPITAL BED/ <i>ÜÇ<br/>MOTORLU PEDIYATRİK<br/>KARYOLA</i>    | MYS-530N                                                                                                                                                                       | 37010 |
| 86817195BEBEKYRX   | BABY CRIB / <i>BEBEK KODU</i>                                                       | MYS-511N                                                                                                                                                                       | 38140 |
| 86817195KRYOLA4DS  | 4 MOTORS HOSPITAL BED/<br><i>DÖRT MOTORLU HASTA<br/>KARYOLASI</i>                   | MYS-5410NE, MYS-5400L,<br>MYS-5410N, MYS-5410Y,<br>MYS-5420N, MYS-5420NE,<br>MYS-5420Y, MYS-5430N,<br>MYS-5510N, MYS-5520N,<br>MYS-5520NE, MYS-5530N,<br>MYS-5535N, MYS-5545NE | 34870 |
|                    | 4 MOTORS PEDIATRIC<br>HOSPITAL BED/ <i>DÖRT<br/>MOTORLU PEDIYATRİK<br/>KARYOLA</i>  | MYS-540N                                                                                                                                                                       | 37010 |
|                    | 4 MOTORS BARIATRIC<br>HOSPITAL BED/ <i>DÖRT<br/>MOTORLU BARIATRİK<br/>KARYOLA</i>   | MYS-5510B                                                                                                                                                                      | 35563 |
| 86817195KRYOLA5DU  | 5 MOTORS HOSPITAL BED/<br><i>BEŞ MOTORLU HASTA<br/>KARYOLASI</i>                    | MYS-5550NE                                                                                                                                                                     | 34870 |
| 86817195KRYOLAHEY  | HYDRAULIC HOSPITAL<br>BED/ <i>HİDROLİK HASTA<br/>KARYOLASI</i>                      | MYS-5310G                                                                                                                                                                      | 34871 |
| 86817195KRYOLAMFA  | MANUAL HOSPITAL BED/<br><i>MANUEL HASTA<br/>KARYOLASI</i>                           | MYS-501BN, MYS-502BN,<br>MYS-502N4, MYS-503N,<br>MYS-503N4                                                                                                                     | 34873 |

|                   |                                                                                              |                                           |       |
|-------------------|----------------------------------------------------------------------------------------------|-------------------------------------------|-------|
|                   | MANUAL PEDIATRIC<br>HOSPITAL BED/ <i>MANUEL<br/>PEDİYATRİK KARYOLA</i>                       | MYS-513N                                  | 37010 |
| 86817195LAMBAV5   | CEILING MOUNTED<br>SURGICAL LIGHT/ <i>AMELİYATHANE TAVAN<br/>LAMBASI</i>                     | MYS-STE1, MYS-STE2,<br>MYS-STE3           | 37332 |
| 86817195MUAYNM6F  | EXAMINATION COUCH/ <i>MUAYENE MASASI</i>                                                     | MYS-720, MYS-721, MYS-<br>722             | 38458 |
| 86817195YMKMA52   | OVER BED TABLE/ <i>HASTA<br/>ÖNÜ YEMEK MASASI</i>                                            | MYS-710, MYS-710T, MYS-<br>710TC, MYS-711 | 35395 |
| 86817195NAKILSXR  | STACKABLE PATIENT<br>TRANSPORT CHAIR/ <i>İÇ<br/>İÇE GEÇEBİLEN HASTA<br/>NAKİL SANDALYESİ</i> | MYS-1050P                                 | 41619 |
| 86817195NEGATOS5A | NEGATOSCOPE/ <i>NEGATOSKOP</i>                                                               | MYS-663N, MYS-664N,<br>MYS-665N, MYS-666N | 36488 |
| 86817195PROKT4N   | PROCTOLOGY TABLE/ <i>PROKTOLOJİ MASASI</i>                                                   | MYS-50                                    | 38601 |
| 86817195SEDEZE    | HYDRAULIC STRETCHER/ <i>HİDROLİKLİ SEDYE</i>                                                 | MYS-600, MYS-650, MYS-<br>950             | 60487 |
|                   | PATIENT TRANSFER<br>STRETCHER/ <i>HASTA<br/>TRANSFER SEDYESİ</i>                             | MYS-800, MYS-850, MYS-<br>850NPT          | 35892 |
| 86817195SRMAS4D   | IV STAND/ <i>SERUM ASKISI</i>                                                                | MYS-K4061, MYS-K4062                      | 36069 |
| 86817195TEKERS3L  | WHEELCHAIR/ <i>TEKERLEKLİ SANDALYE</i>                                                       | MYS-0801, MYS-0804                        | 41622 |
|                   |                                                                                              | MYS-0805                                  | 31162 |
| 86817195YATAK3B   | ANTIDECUBITUS<br>MATTRESS/ <i>ANTİDEKÜBİTİK HASTA<br/>YATAĞI</i>                             | MYS-100S                                  | 47520 |

\*\*\* END OF LIST/ *LİSTENİN SONU*\*\*\*



## DECLARATION OF CONFORMITY

We

**Planmed Oy,  
Sorvaajankatu 7  
00880 Helsinki  
Finland**

declare under our sole responsibility that the product

Extremity Scanner **Planmed Verity**

to which this declaration relates is in conformity with following standards or other normative documents:

|                       |                                                                                                                                                                                    |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IEC 60601-1</b>    | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance                                                                             |
| <b>IEC 60601-1-2</b>  | Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral Standard: Electromagnetic compatibility Requirements and tests                                |
| <b>IEC 60601-1-3</b>  | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment |
| <b>IEC 60601-1-6</b>  | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability                                          |
| <b>IEC 60601-2-54</b> | Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy                 |
| <b>IEC 62304</b>      | Medical device software - Software life cycle processes                                                                                                                            |
| <b>IEC 60601-2-28</b> | Medical electrical equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies for medical diagnosis                                                  |
| <b>ISO 10993-1</b>    | Biological evaluation of medical devices                                                                                                                                           |

following the provisions of **93/42/EEC Directive**.  
Planmed Verity is Class IIb device.

The Notified Body is SGS Fimko Ltd. no 0598.

Helsinki, 2017-12-08



Olli Heikkinen  
Quality Director

# Planmed Verity®

The original weight-bearing CBCT



ENGLISH

Planmed

# Planmed Verity® – extraordinary adaptability

**Planmed Verity®** is a unique 3D imaging solution for orthopedic, head and neck imaging. This mobile all-in-one Cone Beam Computed Tomography (CBCT) scanner provides premium quality images in a compact and beautifully designed package. It is a perfect fit for patients of all sizes – from adult to pediatric patients.

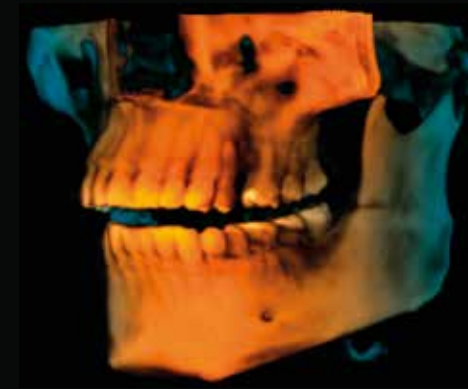
## Exceptional image quality

Planmed Verity's high-quality 3D images capture even the smallest bone structures with minimal interference. Iterative algorithms and a high resolution ensure optimal image quality. Arthrographic examinations with intra-articular contrast provide excellent visualizations of joint disorders.



## Weight-bearing and adaptable

Planmed Verity features a motorized gantry which can be adjusted for height and tilt for the best possible positioning of the patient. The knee, ankle, foot and toes can be imaged in a natural position with the patient standing.



## Versatile head and neck imaging

Planmed Verity's maxillofacial, ENT and dental imaging capabilities make it a versatile tool for imaging centers and hospitals. With Planmed Verity, imaging of the head and neck is both effortless for the staff and comfortable for the patient.

Without Planmeca CALM™



With Planmeca CALM™

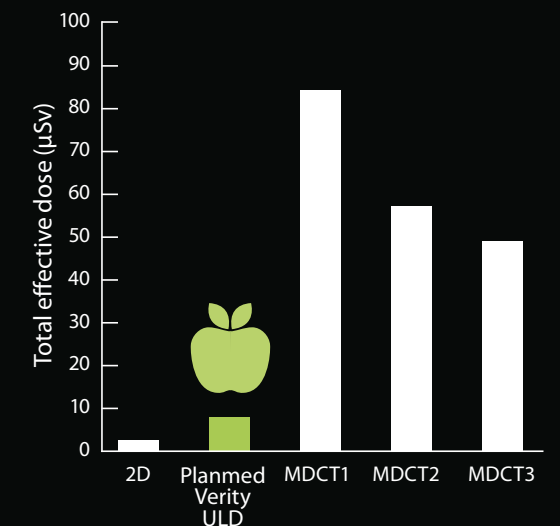


## Movement artefact correction

Planmed Verity can be used with the **Planmeca CALM™** algorithm for patient movement correction. The revolutionary algorithm eliminates the need for retakes by clearing movement artefacts from CBCT images – excellent for imaging livelier patients.

## Ultra low dose 3D imaging

The pioneering **Planmeca Ultra Low Dose™** (ULD) imaging protocol enables CBCT imaging at a significantly lower patient dose than conventional CT imaging – without a reduction in image quality.



Koivisto, J., Kiljunen, T., Wolff, J. and Kortensniemi, M: Assessment of effective radiation dose of an extremity CBCT, MSCT and conventional X ray for knee area using MOSFET dosimeters. Radiat. Prot. Dosim. Advance Access published July 3, 2013, doi: 10.1093/rpd/nct162



# Key features

## Patient positioning

- Positioning camera
- Soft, adjustable gantry
- Anatomy-specific support trays
- Integrated scattered radiation shield

## 3D programs

### Upper extremities

- Elbow
- Arm
- Wrist
- Hand
- Fingers

### Lower extremities (also weight-bearing)

- Knee
- Leg
- Ankle
- Foot
- Toes

### Head and neck

- Ear
- Face
- Jaw
- Neck
- Sinuses
- Teeth

## Technical specifications

|               |                                                         |
|---------------|---------------------------------------------------------|
| Anode voltage | 80–96 kV                                                |
| Anode current | 1–12 mA                                                 |
| Dimensions    | (W x L x H) 76 x 184 x 160 cm / 30 x 72 x 63 in.        |
| Weight        | 350 kg / 770 lbs                                        |
| Field of view | 16 x 13 cm with single scan – stitched up to 16 x 20 cm |
| Voxel sizes   | 200, 400 µm                                             |
| Input         | 100–240V single phase, 10–16A                           |
| Connectivity  | DICOM 3                                                 |

CE 0598  Planned Verity



Watch video :  
Planmed Verity®  
Extremity Scanner

# Planmed

Planmed Oy Sorvaajankatu 7 | 00880 Helsinki | Finland | tel. +358 20 7795 300 | fax +358 20 7795 664 | sales@planmed.com | www.planmed.com



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