KONICA MINOLTA

DRYPRO Σ II

DRY LASER IMAGER

DRYPRO ΣII is a new design in the range of Konica Minolta's Dry Laser Imagers that fits the needs of medical professionals looking for a high resolution table top printer.

The DRYPRO ΣII creates images of unrivalled sharpness, utilizing the latest precision optics from Konica Minolta to produce a 50-µm pixel pitch; the highest available resolution.

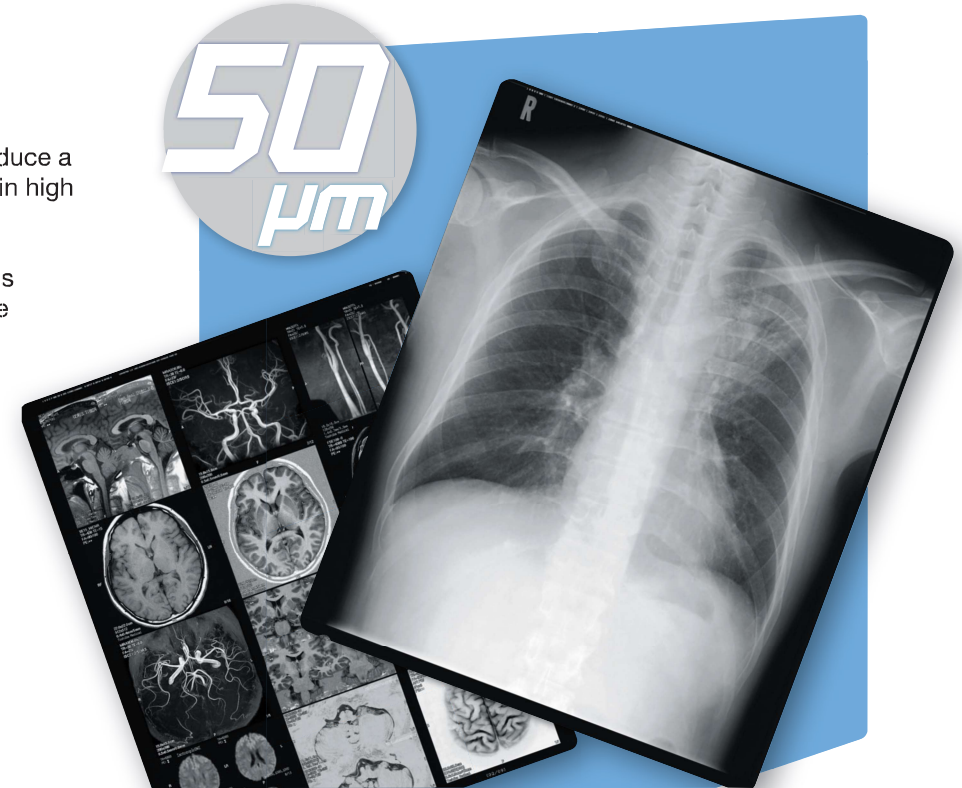
The new compact and highly efficient Laser Imager is easy to operate, offers an intuitive workflow and is available with a wide range of film sizes.

High-Quality images 50-µm

A semiconductor laser is used to produce a 50-µm pixel pitch (508 dpi), resulting in high image resolution.

Powerful image-processing algorithms are utilized to simultaneously optimize both the image smoothness as well as the text sharpness.

Diagnostic clarity is preserved and patient data is always readable, regardless of the print size.



Four film sizes and two trays

Variety of four film sizes: 14x17”, 11x14”, 10x12” and 8x10”.

The DRYPRO ΣII is equipped with two film trays so that two different film sizes can be used simultaneously.

Consistent quality

The DRYPRO ΣII density control function maintains the output density via automatic measurement. The system also automatically calibrates whenever a tray of film with a new lot-number is loaded.

User-friendly design

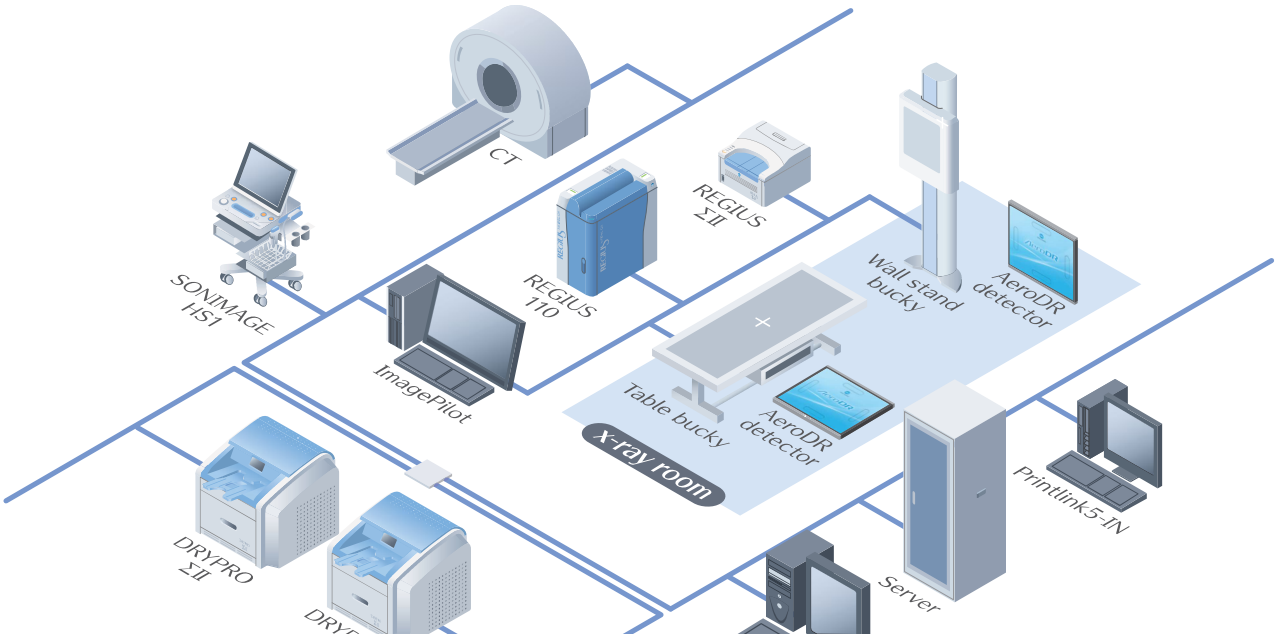
The DRYPRO ΣII is easy to operate and offers an intuitive workflow. Film exchange requires a simple cartridge insertion. The innovative cartridges allow easy film size adjustment and support various modalities such as CR, CT, Ultrasound and MRI.

Space-saving & fast

DRYPRO ΣII is a desktop printer and combines reliability and convenience with remarkable operating efficiency, all in a compact body. It features a footprint as small as 65 x 63 cm² and is designed for use in small clinics and high throughput general hospitals with a speed up to 110 sheets/hour (for 8 x 10”).

Network functions designed for open and flexible environments

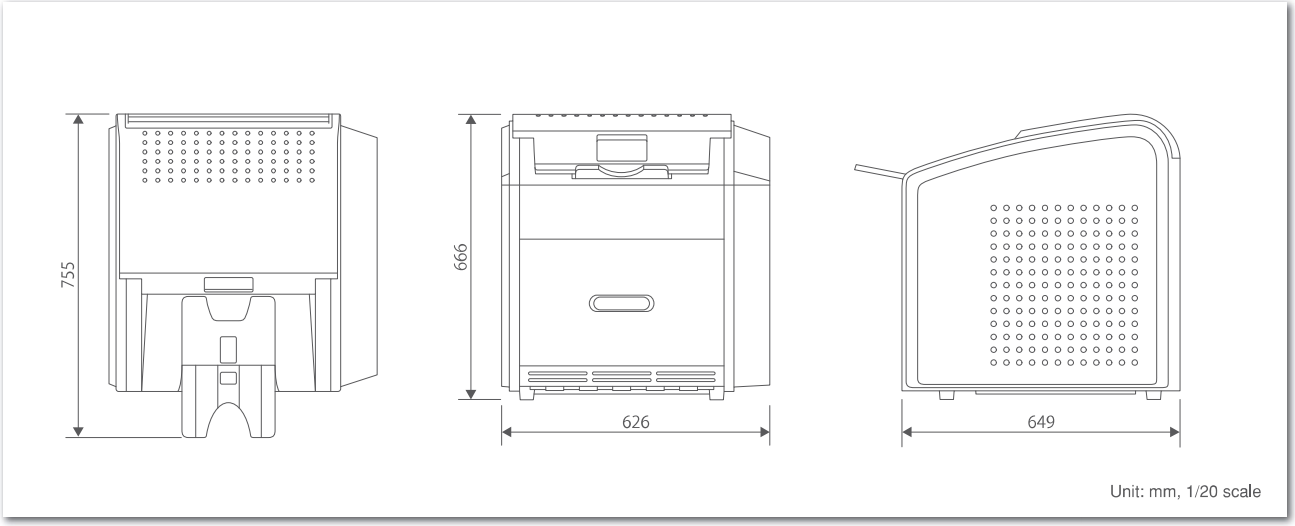
DRYPRO ΣII is a networked imager, capable of connecting directly to DICOM print compliant devices. In addition to DICOM basic grayscale print functions, the DRYPRO ΣII supports Presentation LUT, which enables printed film to more accurately match diagnostic monitors.



PRODUCT SPECIFICATIONS

- Exposure source Semiconductor Laser
- Film size 14”x17”(35x43cm), 11”x14”(28x35cm), 10”x12”(25x30cm), and 8”x10”(20x25cm) selectable
- Film Dry Imaging Recording film SD-S / 125sheets per cartridge
- Pixel size 50µm (508 dpi)
- Processing capability 14x17-inch size sheets approximately 70 sheets/hour
  8x10-inch size sheets approximately 110 sheets/hour
- Network connection Ethernet 10 BASE-T / 100BASE-T / 1000BASE-T
- Film supply Daylight setting
- Number of supply trays 2ch
- Output grades 14bit (16384 grades)
- Network connectivity DICOM Print Management SCP
- Operating condition 15-33ºC 20-80% RH, non-condensing
- Power 90-130V(50/60Hz) 9A / 180-264V (50/60Hz) 4.5A
- Dimensions W:626mm x D:649mm x H:666mm
- Weight 79 kg
- Footprint 0.41m²

DIMENSIONS



Brand Name : DRYPRO Σ II
Type : LASER IMAGER
Model : DRYPRO SIGMA 2

Storing and handling unused film

Unused film should be stored in a cool, dark place (25° or below), where it will not be affected by radiation.

Your Konica Minolta Partner:

MEUN_DPS2_20160912

www.konicaminolta.eu

KONICA MINOLTA

Certificate

KONICA MINOLTA

Medical & Graphic Imaging Europe B.V.

We hereby confirm that

Sergiu Sorocovici

Intermed

has successfully participated in a technical training

from December 17thth to 18th, 2014 for

Drypro Σ, Drypro 832, Drypro 873, Printlink 5 (TTDP&TTDS)

Training content:

• Installation • Configuration

• Adjustments • Troubleshooting

• Basic Application • QC

Munich, December 20th, 2014

Patrick Winkler
Service Manager EMEA

Hans-Joachim Kock
Trainer

TÜVRheinland CERT ISO 9001

Giving Shape to Ideas

KONICA MINOLTA Medical & Graphic Imaging Europe B.V. · Werner-Eckert-Str. 2 · 81829 München

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant
						konica	
DM000349456	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-Q 11X14" MEDICAL FILM 50 SH	A3R7	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349465	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-P 10X12" MEDICAL FILM 125 SH	A5FJ	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349470	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-P 14X17" MEDICAL FILM 125 SH	A5FR	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349460	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-Q 14X17" MEDICAL FILM 125 SH	A3RD	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349455	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-Q 10X12" MEDICAL FILM 125 SH	A3R6	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349454	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-Q 8X10" MEDICAL FILM 125 SH	A3R5	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.
DM000349476	SCANER DE IMAGINI CU LASER		LASER IMAGER DRYPRO SIGMA2		Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.

Document No. 68ERD V.03

KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

Name	KONICA MINOLTA, INC.
Address	1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan
Single Registration Number	JP-MF-000008214

declares, sole responsibility, that the following product

Generic Device Group:	Laser Imagers
Type:	LASER IMAGER
Model (Product Name):	DRYPRO SIGMA 2
Basic UDI-DI:	4560141920000688T
Intended Purpose:	The device is intended for use in the acquisition and process of radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures.
Classification:	Class I, Rule 1, according to Annex VIII of REGULATION (EU) 2017/745
Serial Number:	from 203525 to 999999 (A9R4) from 203535 to 999999 (A9R5)

referred to in this declaration conforms with the following EU law(s):

REGULATION (EU) 2017/745, DIRECTIVE 2014/53/EU and Directive 2011/65/EU

and conforms with the following standard(s):

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021,
EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015,
EN 60601-1-6:2010+A1:2015, EN 60825-1:2007, EN 62366:2008+A1:2015,
EN 62304:2006 for REGULATION (EU) 2017/745,
EN 300 330 V2.1.1 for DIRCTIVE 2014/53/EU,
EN IEC 63000:2018 for Directive 2011/65/EU

and that this declaration is valid upon approval for release of each product.

EU Representative

Name Konica Minolta Business Solutions Europe GmbH
Address Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands
Single Registration Number NL-AR-000002026

Signed for and on behalf of manufacturer:

Tokyo Japan, 2024-06-14
(Place and date of issue)
YOSHINORI SATO
General Manager,
Quality Assurance Operations
Healthcare Business Headquarters
(Name, function)

DocuSigned by Yoshinori Sato
Yoshinori Sato
この文書を承認する
6 14, 2024 | 10:40:55 午前 JST
CC41882571A04791AA483438368077D5

(Signature of equivalent authorized by the manufacturer)

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2003379-1

Manufacturer: **KONICA MINOLTA, INC.**
1 Sakura-machi, Hino-shi, Tokyo,
191-8511 Japan

EUDAMED Single Registration No.: JP-MF-000008214

Products: Products of class IIa:

Z110603 - PICTURE ARCHIVING AND COMMUNICATION SYSTEMS
Z110401 - ULTRASOUND SCANNERS
Z110311 - DIRECT DIGITAL X-RAY SYSTEMS
Z11031182 - DIRECT DIGITAL X-RAY SYSTEMS – SOFTWARE
Z110402 - ULTRASOUND PROBES

Authorised representative(s): Konica Minolta Business Solutions Europe GmbH
Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands

Certificate history		
Revision:	Description:	Issue date:
1	Initial issue	2021-07-21
2	Added code Z110311 and Z11031182	2021-09-01
3	Added code Z110402	2023-08-01

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 150278697-307

Effective date: 2023-08-01

Expiry date: 2026-07-20

Issue date: 2023-08-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2003379-1
Certificate Holder:	KONICA MINOLTA, INC. 1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan
Scope:	Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic Ultrasound Transducers, Ultrasound Needle Guides, Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Software for Pulse Oximeters, Physiological patient Monitor, Jaundice Meters and Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	150297671-301
Effective date:	2025-04-19
Expiry date:	2028-04-18
Issue date:	2025-01-28

Replaces certificate SX 2003379-1 issued 2024-02-05

This certificate can be validated on https://www.certipedia.com

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche

TÜVRheinland®

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

Design, Development, Manufacture and Distribution of
Laser Imagers,
Diagnostic X-ray Systems,
Diagnostic Ultrasound Systems and
Pulse Oximeter Probes

Manufacture and Distribution of
Thermal Imagers,
Medical Imaging Films and
X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use)

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01-1	c/o KONICA MINOLTA, INC. Tokyo site 1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan	Design and Development of Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Software for Pulse Oximeters, Physiological patient Monitor, Jaundice Meters and Fluoroscopic Image Storage Devices (Cassette) Design, Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes Distribution of Thermal Imagers, Medical Imaging Films and X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use) Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic Ultrasound Transducers, Ultrasound Needle Guides and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche

TÜVRheinland®

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

The scope of certification also covers the following sites:

/01-2	c/o KONICA MINOLTA, INC. Tokyo site 2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505 Japan	Design and Development of Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Software for Pulse Oximeters, Physiological patient Monitor Jaundice Meters and Fluoroscopic Image Storage Devices (Cassette) Design, Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes Distribution of Thermal Imagers, Medical Imaging Films, X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use) Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic Ultrasound Transducers, Ultrasound Needle Guides and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

The scope of certification also covers the following sites:

/01-3	c/o KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Tokyo site 1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan	Design and Development of Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Software for Pulse Oximeters, Physiological patient Monitor, Jaundice Meters and Fluoroscopic Image Storage Devices (Cassette) Design, Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes Distribution of Thermal Imagers, Medical Imaging Films and X-ray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use) Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic Ultrasound Transducers, Ultrasound Needle Guides and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

The scope of certification also covers the following sites:

/02	c/o KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Sayama site 2-2-1 Hirosedai, Sayama-shi, Saitama, 350-1328 Japan	Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems, Diagnostic Ultrasound Transducers, Ultrasound Needle Guides, Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Pulse Oximeter Probes, Software for Pulse Oximeters, Physiological patient Monitor, Jaundice Meters and Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate) Design and development of packaging design for Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems, Diagnostic Ultrasound Transducers, Ultrasound Needle Guides, Picture Archiving and Communication Systems (PACS), Software for PACS, Diagnostic X-ray Digital Imaging System Workstation, Software for Diagnostic X-ray Digital Imaging System Workstation, Print Management Systems, Pulse Oximeters, Pulse Oximeter Probes, Software for Pulse Oximeters, Physiological patient Monitor, Jaundice Meters and

DAkkS Deutsche

TÜVRheinland®

SXE24-10

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2003379-1

Certificate Holder: KONICA MINOLTA, INC.
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan

The scope of certification also covers the following sites:

Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate).

/03	c/o KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Kuki site 6201-6 Sanga, Shobu-cho, Kuki-shi, Saitama, 346-0104 Japan	Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Thermal Imagers, Medical Imaging Films and X-ray Films (X-ray Films for General Radiography and X-ray Films for Photofluorography and Dental X-ray Films for General Use)

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche

TÜVRheinland®