



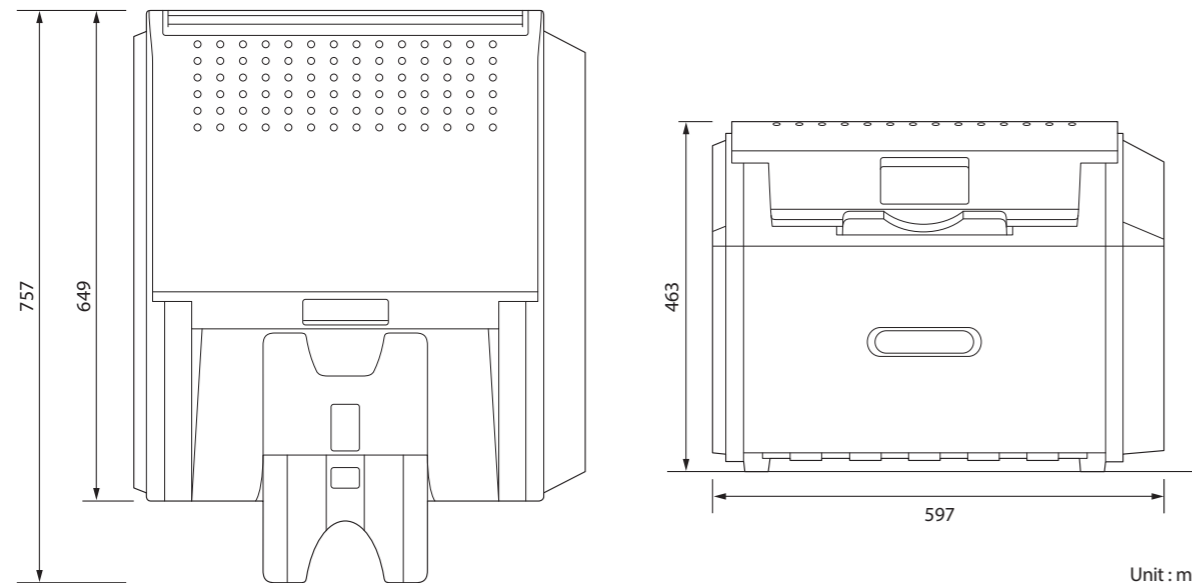
KONICA MINOLTA

DRYPRO Σ

DRYPRO SIGMA Specifications

- **Laser Source**
Semiconductor Laser
- **Film Size**
14"x17" (35x43 cm), 11"x14" (28x35 cm), 10"x12" (25x30 cm), and 8"x10" (20x25 cm) selectable
- **Film**
Dry Imaging recording film SD-5
- **Image Format**
1,2,4,6,8,9,12,15,16,20,24,30,35
- **Image Memory**
2 GB
- **Pixel Size**
78 μm
- **Processing capability**
Up to 45 films per hour (14x17" / 35x43 cm)
- **Input interface**
Ethernet 10/100/1000 Base-T
• Integrated DICOM interface supports printing from DICOM print modalities
* Connect non-DICOM modalities using PrintLink IV, ID
- **Operating conditions**
15 - 33 °C (59-91 F) 20 - 80 % RH, non-condensing
- **Power**
100-120 V ±10% (50/60 HZ) 9 A
200-240 V ±10% (50/60 HZ) 5 A
- **Dimensions / Weight**
W597 mm X D649 mm X H463 mm / 54 kg
- **Footprint**
0.39 m²

DRYPRO SIGMA Outer Dimensions



Unit : mm 1/10 scaled

*Specifications are subject to change without prior notice.



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KONICA MINOLTA BUSINESS SOLUTIONS EUROPE GMBH

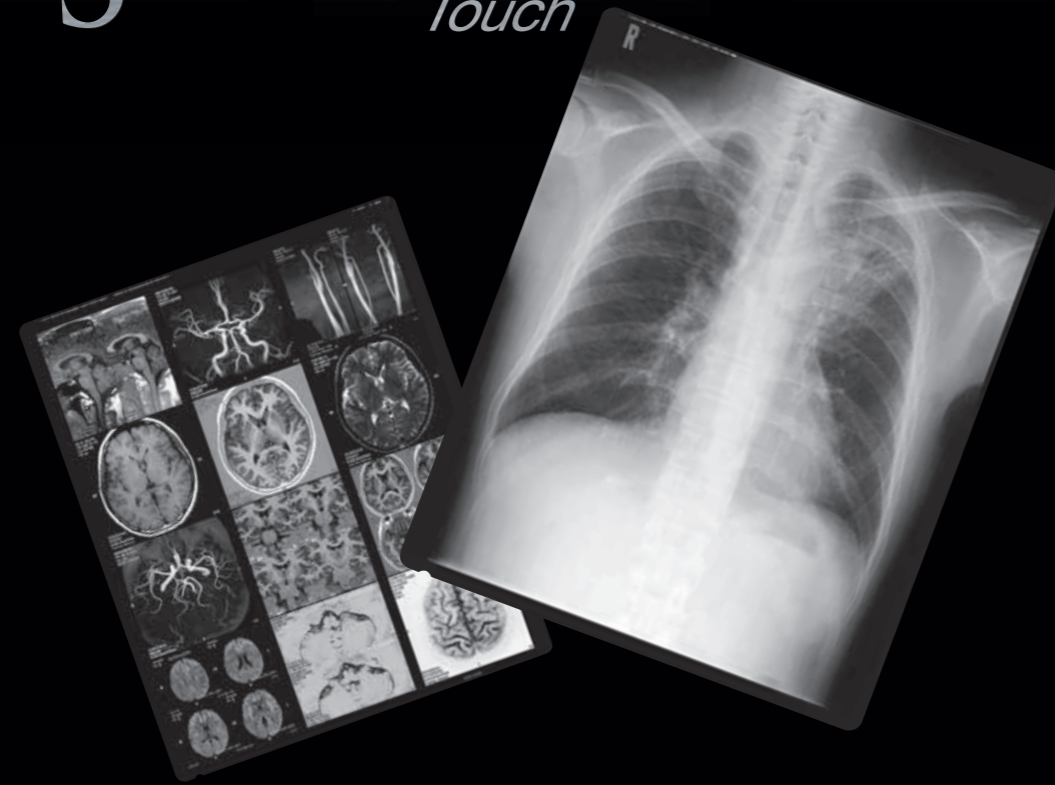
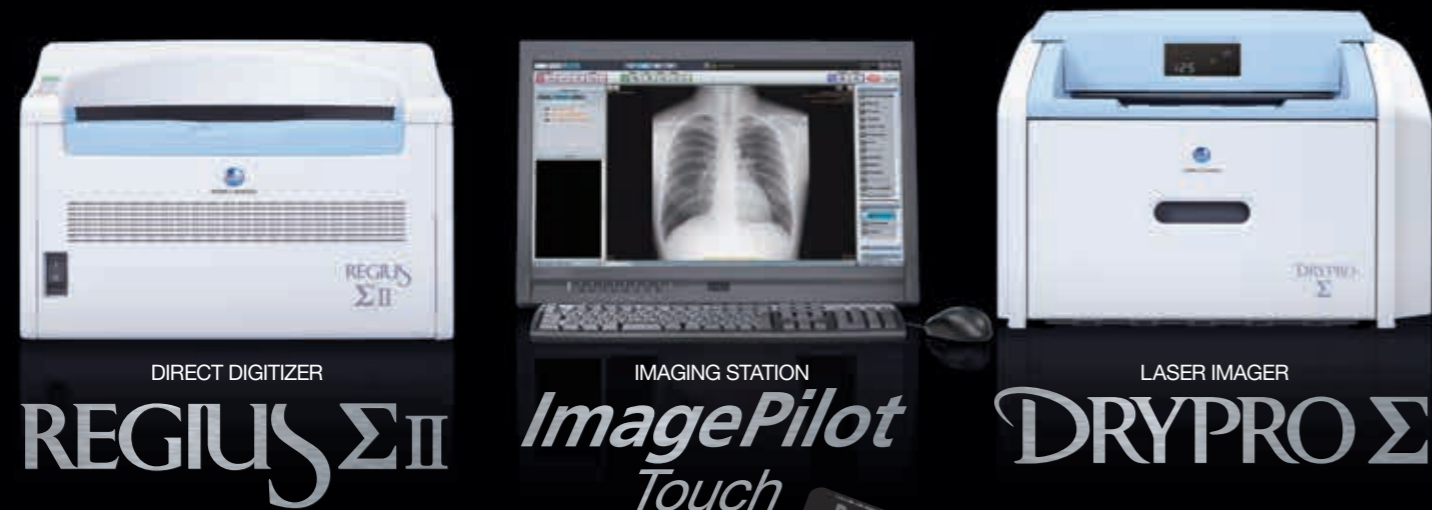
Hoogoorddreef 9, 1101BA Amsterdam, The Netherlands
info-nl@mg.konicaminolta.eu - www.konicaminolta.eu/healthcare

Distributed by :

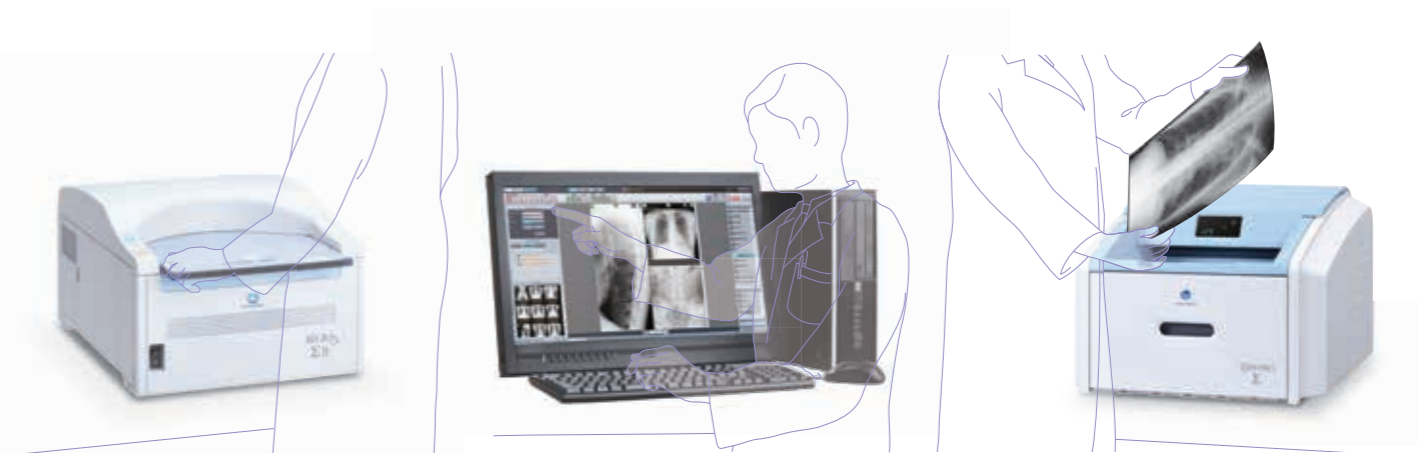
Giving Shape to Ideas

SIGMA PACKAGE

DRYPRO SIGMA is a tabletop DRY Laser Imager that adds true customer value to all institutions using film. Digital imaging is made easy and efficient, especially when combined with REGIUS SIGMA II and ImagePilot. One step is all it takes to take you to the digital world. The compact and powerful SIGMA package services make it all possible.



From patient registration to film output, Konica Minolta provides a complete workflow.



I. Digitize

Just insert an exposed cassette into the REGIUS SIGMA II CR reader. Image Pilot then automatically processes the image for optimal diagnostic viewing. REGIUS SIGMA II delivers up to 60 plates per hour (14x17").

II. Print View

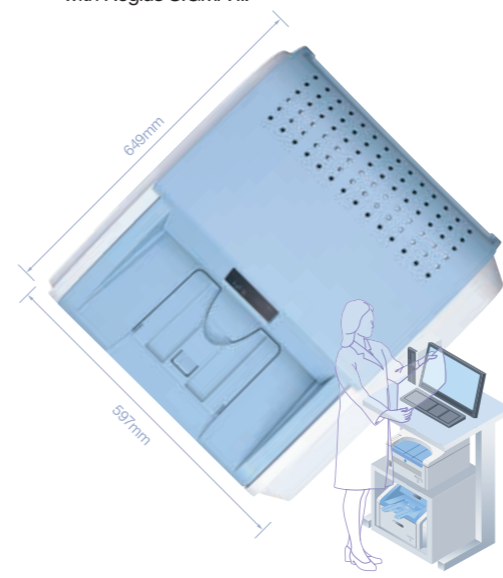
ImagePilot has a Print Compose mode which allows you to adjust images, layouts, and annotations freely. Since adjustments can be made on the image acquisition screen without needing to switch to another screen, the task can be completed in a much shorter time.

III. Print

The DRYPRO SIGMA outputs the films up to 45 sheets (14x17") per hour. Drypro SIGMA has four film sizes available, which can be transposed based on user needs.

Compact Design

DRYPRO SIGMA is a desktop DRY Laser Imager. It features a compact footprint as small as 65x60 cm. It is designed to seamlessly integrate into various environments especially when combined with Regius SIGMA II.



Four film sizes and easy loading process

Users can use up to four film sizes for different purposes. Open the front cover, retrieve the film inside, and load your choice of film size. Replacing the film is easy with this simple process.

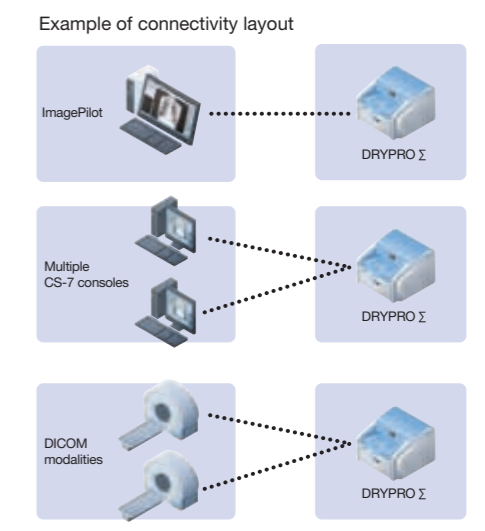


User-friendly

DRYPRO SIGMA is easy to operate and requires no hands-on training upon installation offering intuitive usability.

DICOM PRINTER

DRYPRO SIGMA can easily connect with other CR or DR consoles, CT or MR, in addition to ImagePilot. Non-DICOM images can be imported easily using ImagePilot and then be printed using DRYPRO SIGMA.





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 17th 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



Giving Shape to Ideas

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...									
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						konica			
DM000349462	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-QM 8X10" MEDICAL FILM 125 SH	A3R3	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.	Rg04-000097	15-04-2022
DM000349475	SCANER DE IMAGINI CU LASER		LASER IMAGER DRYPRO SIGMA		Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.	Rg04-000097	15-04-2022
DM000349457	FILME PENTRU REPRODUCERE DIN TEHNOLOGII LASER		SD-Q 11X14" MEDICAL FILM 125 SH	A3R8	Japonia	KONICA MINOLTA, INC.	INTERMED S.R.L.	Rg04-000097	15-04-2022



KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

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

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 A9R4-201363 to A9R4-999999 (A9R4)
from A9R5-201363 to A9R5-999999 (A9R5)

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

REGULATION (EU) 2017/745, confirmed by the procedure of its Annex IX,
DIRECTIVE 2014/53/EU and Directive 2011/65/EU

and conforms with the following standard(s):

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008,
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 DIRECTIVE 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, 2021-04-22
(Place and date of issue)
HAJIME NOZAWA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

A handwritten signature in black ink, appearing to read 'Hajime Nozawa'.

(Signature of equivalent authorized by the manufacturer)

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2003379-1

Organization: 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), Radiographic Film Processors, 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 and Jaundice Meters

Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate)

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

Manufacture and Distribution of 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)

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.: 150247687-301
Effective date: 2022-04-19
Expiry date: 2025-04-18
Issue date: 2022-04-11



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

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2003379-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01-1	c/o KONICA MINOLTA, INC. Tokyo site 1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan	<p>Design and Development of Radiographic Film Processors, 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 and Jaundice Meters</p> <p>Design and Development of Fluoroscopic Image Storage Devices (Cassette)</p> <p>Design and Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes</p> <p>Distribution of 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)</p> <p>Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic Ultrasound Transducers and Ultrasound Needle Guides</p> <p>Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate and Cassette Plate)</p>

Report No.: 150247687-301
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Michiaki Aihara
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TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2003379-1

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

/01-2 c/o KONICA MINOLTA, INC.
Tokyo site
2970 Ishikawa-machi,
Hachioji-shi, Tokyo
192-8505 Japan

Design and Development of Radiographic Film Processors, 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 and Jaundice Meters

Design and Development of Fluoroscopic Image Storage Devices (Cassette)

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

Distribution of 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 and Ultrasound Needle Guides

Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate and Cassette Plate)

Report No.: 150247687-301
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M. Aihara

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

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2003379-1

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

The scope of certification also covers the following:

- | | | |
|-------|--|--|
| /01-3 | c/o KONICA MINOLTA
TECHNOPRODUCTS CO.,
LTD.
Tokyo site
1 Sakura-machi,
Hino-shi, Tokyo,
191-8511 Japan | Design and Development of Radiographic Film Processors, 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 and Jaundice Meters |
| | | Design and Development of Fluoroscopic Image Storage Devices (Cassette) |
| | | Design and Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes |
| | | Distribution of 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 and Ultrasound Needle Guides |
| | | Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate and Cassette Plate) |

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M. Aihara

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

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2003379-1

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

The scope of certification also covers the following:

/02	c/o KONICA MINOLTA TECHNOPRODUCTS CO., LTD. Sayama site 2-2-1 Hirose-dai, Sayama-shi, Saitama 350-1328 Japan	Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, 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 and Jaundice Meters Manufacture of 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) and Laser Imagers Manufacture of 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)

Report No.: 150247687-301
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 Expiry date: 2025-04-18
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M. Aihara

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