

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

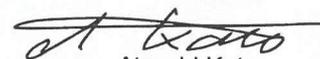
Effective date: 2025-04-19

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

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 Tillystraße 2 · 90431 Nürnberg · Germany

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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)

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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	<p>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)</p> <p>Design, Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes</p> <p>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)</p> <p>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)</p>

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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)

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 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	<p>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)</p> <p>Design, Development and Distribution of Laser Imagers, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Pulse Oximeter Probes</p> <p>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)</p> <p>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)</p>
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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	<p>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)</p> <p>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</p>
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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)
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