

# 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



*M. Aihara*

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



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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>

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191-8511 Japan

/01-2	c/o KONICA MINOLTA, INC. Tokyo site 2970 Ishikawa-machi, Hachioji-shi, Tokyo 192-8505 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>
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1 Sakura-machi  
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191-8511 Japan

The scope of certification also covers the following:

- |   |   |
|---|---|
| <p>/01-3 c/o KONICA MINOLTA<br/>TECHNOPRODUCTS CO.,<br/>LTD.<br/>Tokyo site<br/>1 Sakura-machi,<br/>Hino-shi, Tokyo,<br/>191-8511 Japan</p> | <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> |
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191-8511 Japan

The scope of certification also covers the following:

- |     |   |   |
|-----|---|---|
| /02 | c/o KONICA MINOLTA<br>TECHNOPRODUCTS CO.,<br>LTD.<br>Sayama site<br>2-2-1 Hirose-dai,<br>Sayama-shi, Saitama<br>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<br><br>Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate) |
| /03 | c/o KONICA MINOLTA<br>TECHNOPRODUCTS<br>CO., LTD.<br>Kuki site<br>6201-6 Sanga, Shobu-cho,<br>Kuki-shi, Saitama<br>346-0104 Japan | Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems) and Laser Imagers<br><br>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)  |

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