

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
KONICA MINOLTA, INC.
1 Sakura-machi, Hino-shi,
Tokyo
191-8511 Japan

has established and applies a quality management system for medical devices
for the following scope:

**In accordance with EN ISO 13485:2016 Medical devices
-Quality management systems-Requirements for regulatory
purposes (ISO 13485:2016)
See attachment(s) for the scope**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-03-31
 Certificate Registration No.: SX 60148387 0001
 An audit was performed. Report No.: 12031254 039
 This Certificate is valid until: 2022-04-18

Certification Body



Date 2020-03-31


Masahiro Asami

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
 Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148387 0001
Report No.: 12031254 039

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 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.

The scope continues to the next attachment.

Certification Body



Date: 2020-03-31


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148387 0001
Report No.: 12031254 039

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

Scope:

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)

Certification Body



Date: 2020-03-31



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/7, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148387 0001
Report No.: 12031254 039

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

Scope:

Sites included:

Tokyo site
 KONICA MINOLTA, INC.
 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan
 2970 Ishikawa-machi, Hachioji-shi, Tokyo, 192-8505, Japan

Scope:

Design and Development of 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 and Jaundice Meters.

The scope continues to the next attachment.

Certification Body**Date:** 2020-03-31

Masahiro Asami

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148387 0001
Report No.: 12031254 039

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

Scope:

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

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)

Certification Body



Date: 2020-03-31


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60148387 0001
Report No.: 12031254 039

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

Scope:

Sites included:

Tokyo site
KONICA MINOLTA TECHNOPRODUCTS CO., LTD.
1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

Scope:
Manufacture of Diagnostic Ultrasound Transducers and
Ultrasound Needle Guides.

Manufacture of Fluoroscopic Image Storage Devices
(Plate and Cassette Plate)

Certification Body



Date: 2020-03-31



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60148387 0001
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Organization: KONICA MINOLTA, INC.
1 Sakura-machi, Hino-shi,
Tokyo
191-8511 Japan

Scope:

Sites included:

Sayama site
KONICA MINOLTA TECHNOPRODUCTS CO., LTD.
2-2-1 Hirosedai, Sayama-shi, Saitama, 350-1328, Japan

Scope:


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 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 and Jaundice Meters.

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

Certification Body



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

Scope:

Sites included:

Kuki site
KONICA MINOLTA TECHNOPRODUCTS CO., LTD.
6201-6 Sanga, Shobu-cho, Kuki-shi, Saitama, 346-0104, Japan

Scope:

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)

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Masahiro Asami