

# 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



**TỔNG GIÁM ĐỐC**  
*Trần Thị Mỹ Duyên*

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

**See attachments for scope of certification**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-04-19  
Certificate Registration No.: SX 60104786 0001  
An audit was performed. Report No.: 12031254 001  
This Certificate is valid until: 2019-04-18

Certification Body



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

Date 2016-04-18



Dipl.-Ing. S. Pane

**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

Doc. 1/5, Rev. 0

**Attachment to  
 Certificate**

**Registration No.:** SX 60104786 0001  
**Report No.:** 12031254 001

**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), Laser Imagers, Radiographic Film Processors, Diagnostic Ultrasound Systems and Transducers, Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS) and Print Management Systems

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

Distribution of Diagnostic X-ray Systems, 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)

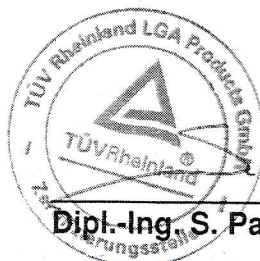
**Certification Body**



**DAkkS**

Deutsche  
 Akkreditierungsstelle  
 D-ZM-14169-01-02

**Date: 2016-04-19**



**Dipl.-Ing. S. Pane**

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**TÜV Rheinland**  
**LGA Products GmbH**  
 Tillystraße 2, 90431 Nürnberg

Doc. 2/5, Rev. 0

**Attachment to  
 Certificate**

**Registration No.:** SX 60104786 0001  
**Report No.:** 12031254 001

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

**Scope:**

Sites included:

Hino site  
 KONICA MINOLTA, INC., Healthcare Business Unit  
 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

Scope:

- Design and Development of Diagnostic Ultrasound Systems and Transducers, Picture Archiving and Communication Systems (PACS), Fluoroscopic Image Storage Devices (Plate and Cassette Plate), and Software for Picture Archiving and Communication Systems (PACS)
- Distribution of Diagnostic X-ray Systems, Medical Imaging Films, Xray Films (X-ray Films for General Radiography, X-ray Films for Photofluorography and Dental X-ray Films for General Use)

**Certification Body**



**Dipl.-Ing. S. Pane**

**Date: 2016-04-19**

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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 3/5, Rev. 0

**Attachment to  
 Certificate**

**Registration No.:** SX 60104786 0001  
**Report No.:** 12031254 001

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

**Scope:**

Sites included:

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

Scope:

- Manufacture of Diagnostic Ultrasound Transducers and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)

**Certification Body**



**Dipl.-Ing. S. Pane**

**Date: 2016-04-19**

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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 4/5, Rev. 0

**Attachment to  
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**Registration No.:** SX 60104786 0001  
**Report No.:** 12031254 001

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

**Scope:**

Sites included:

Hachioji site  
KONICA MINOLTA, INC., Healthcare Business Unit  
2970 Ishikawa-machi, Hachioji-shi, Tokyo, 192-8505, Japan

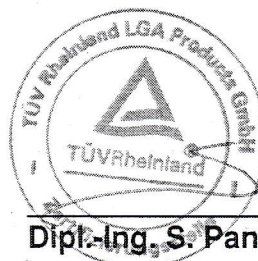
Scope:

- Design and Development of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Picture Archiving and Communication Systems (PACS), Print Management Systems and Fluoroscopic Image Storage Devices (Cassette and Cassette Plate)

**Certification Body**



**Date: 2016-04-19**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 5/5, Rev. 0

**Attachment to  
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**Registration No.:** SX 60104786 0001  
**Report No.:** 12031254 001

**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:

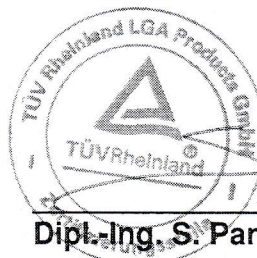
- Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Diagnostic Ultrasound Systems, Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS), Print Management Systems and Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate)

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**Certification Body**



**Date: 2016-04-19**



**Dipl.-Ing. S. Pane**