

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60111250 0001

Report No.: 12031254 002

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

Products: Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Transducers, Pulse Oximeters
(see attachments for sites and products included)

Replaces Approval, Registration No.: HD 60100408 0001

Expiry Date: 2021-01-22

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-11-23

Date: 2016-11-23

Notified Body

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60111250 0001
Report No.: 12031254 002

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

Products and Sites included:

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

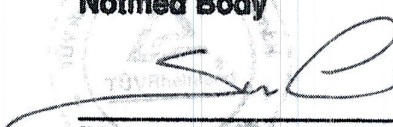
- Diagnostic X-ray Systems
- Diagnostic Ultrasound Systems and Tranceducers
- Pulse Oximeters

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


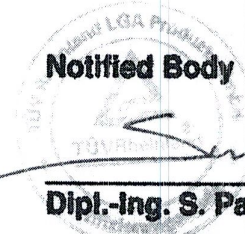
- Diagnostic Ultrasound Tranceducers

Date: 2016-11-23

Notified Body



Dipl.-Ing. S. Pane



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60111250 0001
Report No.: 12031254 002

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

Products and Sites included:

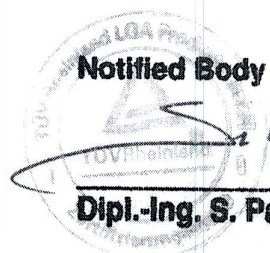
Hachioji site
KONICA MINOLTA, INC., Healthcare Business Unit
2970 Ishikawa-machi, Hachioji-shi, Tokyo, 192-8505, Japan

- Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems)
- Pulse Oximeters

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

- Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems)
- Diagnostic Ultrasound Systems

Date: 2016-11-23



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89040**

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

including the locations according to annex

Scope: Design, Development and Manufacture of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Diagnostic X-ray Systems, Diagnostic Ultrasound Systems and Transducers, 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, Oxygen Saturation Monitors and Jaundice Meters. Design, Development and Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate) 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) Design, Development and Manufacture of Radiation detective phosphor plates (scintillator)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2019-04-12 until 2022-04-11.
First certification 2003

2019-04-12


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Standard: **ISO 9001:2015**

No.	Location	Scope
/01	KONICA MINOLTA, INC. Hino site	Design, Development and Manufacture of Diagnostic Ultrasound Systems and Transducers and Fluoroscopic Image Storage Devices (Plate and Cassette Plate)
	KONICA MINOLTA TECHNOPRODUCTS CO., LTD., Hino Site	Design and Development of Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS)
	1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan	Manufacture of Laser Imagers, Diagnostic X-ray Systems, Pulse Oximeters and Oxygen Saturation Monitors
		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),
		Design and Development of Radiation detective phosphor plates (scintillator)

Annex to certificate

Standard: **ISO 9001:2015**

Certificate Registr. No.: **09 100 89040**

No.	Location	Scope
/02	KONICA MINOLTA, INC. Hachioji site 2970 Ishikawa-cho Hachioji-shi, Tokyo, 192-8505, Japan	Design and Development of Direct Digitizers (Computed Radiography Systems and Digital Radiography Systems), Laser Imagers, Radiographic Film Processors, Diagnostic X-ray Systems, 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, Oxygen Saturation Monitors and Jaundice Meters. Design and Development of Fluoroscopic Image Storage Devices (Cassette and Cassette Plate)