

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60108665 0001

Report No.: 12031254 001

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

Products: Medical Devices for Radiography and Fluoroscopy Applications
(see attachments for sites and products included)
Replaces Approval, Registration No.: DD 60084941 0001

Expiry Date: 2021-01-22

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III 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.: DD 60108665 0001
Report No.: 12031254 001

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

- X-ray films for General Radiography
- Dental X-ray films for General use

Hino site

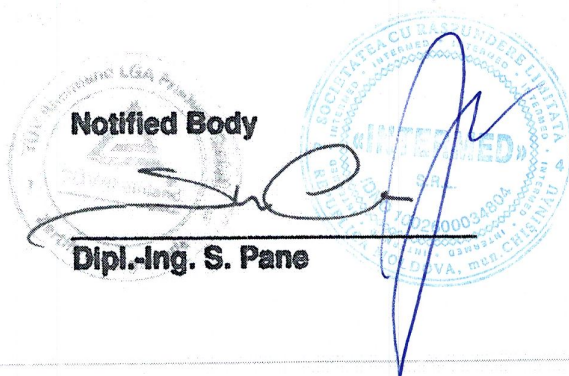
KONICA MINOLTA TECHNOPRODUCTS CO., LTD.
1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

- Fluoroscopic Image Storage Devices
(Plate and Cassette Plate)

Date: 2016-11-23

Notified Body

Dipl.-Ing. S. Pane



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 0101627

Certificate Holder:



KONICA MINOLTA

**KONICA MINOLTA Business
Solutions Europe GmbH
Healthcare Division**
Hoogoorddreef 9
1101 BA Amsterdam
Netherlands

including the location
**Konica Minolta Business
Solutions Europe GmbH
Healthcare Division**
Werner-Eckert-Str. 2
81829 München
Germany

Scope: Trade including import and export and the provision of associated technical support, related to medical products and systems for medical imaging

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

Validity: The certificate is valid from 2017-05-13 until 2020-05-12.
First certification 2011

2017-04-12


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



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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


TUV Rheinland Cert GmbH
Am Grauen Stein : 51105 Köln

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Annex to certificate

Standard: **ISO 9001:2015**

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

| No. | Location | Scope |
|-----|--|---|
| /01 | KONICA MINOLTA, INC. Hino site KONICA MINOLTA TECHNOPRODUCTS CO., LTD., Hino Site 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan | Design, Development and Manufacture of Diagnostic Ultrasound Systems and Transducers and Fluoroscopic Image Storage Devices (Plate and Cassette Plate) Design and Development of Picture Archiving and Communication Systems (PACS), Software for Picture Archiving and Communication Systems (PACS) 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) |

Annex to certificate

Standard: **ISO 9001:2015**

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

| No. | Location | Scope |
|-----|--|---|
| /03 | KONICA MINOLTA TECHNOPRODUCTS CO., LTD., Sayama Site 2-2-1 Hirosedai, Sayama-shi, Saitama, 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, 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 and Jaundice Meters. Manufacture of Fluoroscopic Image Storage Devices (Plate, Cassette and Cassette Plate) and Radiation detective phosphor plates (scintillator) |