

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

Registration No.: DD 60143023 0001

Report No.: 12031254 027

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 60147920 0001

Expiry Date: 2024-05-26

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: 2020-06-12

Date: 2020-06-12



Notified Body

M. Aihara
M.Sc. M. Aihara

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

**Attachment to
Certificate**

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Tokyo
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Products and 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

-X-ray Films for General Radiography
-Dental X-ray Films for General Use

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

-Fluoroscopic Image Storage Devices (Plate and Cassette
Plate)

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

-Fluoroscopic Image Storage Devices (Plate and Cassette
Plate)
-Software for Picture Archiving and Communication Systems
(PACS)
-Software for Diagnostic X-ray Digital Imaging System
Workstation

Notified Body

Date: 2020-06-12


M.Sc. M. Aihara

