

**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**

**Registration No.:** DD 60143023 0001  
**Report No.:** 12031254 027

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

**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**

