

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

Registration No.: HD 60149934 0001

Report No.: 12031254 026

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 Diagnostic Ultrasound Transducers (see attachments for sites and products included)

Replaces Approval, Registration No.: HD 60147914 0001

Expiry Date: 2024-05-26

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: 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.: HD 60149934 0001
Report No.: 12031254 026

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

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

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

- Diagnostic Ultrasound Transducers

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
- Diagnostic Ultrasound Transducers

Date: 2020-06-12

Notified Body


M.Sc. M. Aihara

