

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

**Registration No.:** HD 60147504 0001

**Report No.:** 12031273 015

**Manufacturer:** Shimadzu Corporation  
Medical Systems Division  
1, Nishinokyo-Kuwabaracho  
Nakagyo-ku, Kyoto  
604-8511 Japan

**Products:** Diagnostic X-Ray Devices, Angiographic X-Ray Diagnostic Systems, X-Ray Tube Assemblies  
Near Infrared Fluorescence Imaging System and  
Workstation software for Diagnostic X-Ray Systems

Replaces Approval, Registration No.: HD 60130116 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:** 2020-06-01

**Date:** 2020-06-01



**Notified Body**

  
Takashi Matsuda

**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 60147504 0001  
**Report No.:** 12031273 015

**Manufacturer:** Shimadzu Corporation  
Medical Systems Division  
1, Nishinokyo-Kuwabaracho  
Nakagyo-ku, Kyoto  
604-8511 Japan

**Site included:**

Shimadzu Corporation Sanjo Works  
(Shimadzu Corporation Sanjo Factory)

1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto,  
604-8511, Japan

**Date:** 2020-06-01



**Notified Body**

  
**Takashi Matsuda**