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# 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.**

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Doc. 1/1, Rev. 0

# 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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

**Notified Body**

T. Matsuda

**Takashi Matsuda**