EC Certificate

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

Registration No.: HD 60130116 0001

Report No.: 12031273 009

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 Camera System, Workstation software for Diagnostic X-Ray Systems

Replaces Approval, Registration No.: HD 60109982 0001

Expiry Date: 2021-05-25

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: 2018-07-06

Date: 2018-07-06

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

Digitally signed by Botnaru Andrei
Date: 2019.06.24 10:15:27 EEST
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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60130116 0001
Report No.: 12031273 010

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-03-19

M.Sc. M. Aihara