

## **EC** Certificate

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

Registration No.: HD 60125549 0001

Report No.: 12031293 003

Manufacturer: Canon Medical Systems Corporation

Otawara-shi, Tochigi 324-8550

1385, Shimoishigami

Japan

**Products:** see attachment for products included

Replaces Approval, Registration No.: HD 60113513 0001

**Expiry Date:** 2021-09-09

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:

2018-01-04

Date:

2018-01-04

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified Body

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 Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

HD 60125549 0001

Report No.:

12031293 003

Manufacturer:

**Canon Medical Systems Corporation** 

1385, Shimoishigami

Otawara-shi, Tochigi 324-8550

Japan

## Products included:

- Mobile and Stationary Diagnostic X-Ray Systems
- Mobile and Stationary Fluoroscopic X-Ray Systems
- X-Ray Computed Tomography Systems
- Diagnostic Ultrasound Systems
- Magnetic Resonance Imaging Systems
- Positron CT System combined with X-ray CT Scanner
- Workstation Software for Diagnostic X-Ray Systems
- Workstation Software for Diagnostic X-Ray Computed Tomography Systems
- Workstation Software for Diagnostic Ultrasound Systems
- Workstation Software for Diagnostic Magnetic Resonance Imaging Systems

Date: 2018-01-04

Notified Body
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