

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

Registration No.: HD 60143874 0001

Report No.: 12031293 014

Manufacturer: Canon Medical Systems Corporation
1385, Shimoishigami
Otawara-shi, Tochigi
324-8550 Japan

Products: see attachment for products included

Replaces Approval, Registration No.: HD 60125549 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: 2019-11-07

Date: 2019-11-07



Notified Body

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 60143874 0001
Report No.: 12031293 014

Manufacturer: Canon Medical Systems Corporation
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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



Notified Body

Date: 2019-11-07

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