# 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
1385, Shimoishigami
Otawara-shi, Tochigi 324-8550
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

**Notified Body**

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 Matei Vasile
Date: 2021.08.12 09:35:09 EEST
Reason: MoldSign Signature
Location: Moldova

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Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**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

TÜV Rheinland LGA Products GmbH Zertifizierung TÜVRheinland®

**Notified Body**

M. Aihara

**M.Sc. M. Aihara**