

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices  
for the following scope:

**Design, Development, Manufacture, Installation, Maintenance,  
Distribution and Servicing of Medical Imaging Systems,  
Related Hardware and Software**  
**(See attachment for products and additional site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-09-10  
Certificate Registration No.: SX 60142527 0001  
An audit was performed. Report No.: 12031293 011  
This Certificate is valid until: 2022-09-09

Certification Body



Date 2019-09-06

  
M.Sc. M. Aihara

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60142527 0001  
**Report No.:** 12031293 011

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

**Scope:**

**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
- Nuclear medicine imaging systems
- 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

**Certification Body**



**Date:** 2019-09-09

*M. Aihara*  
**M.Sc. M. Aihara**