

# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Hitachi, Ltd.  
Medical System Operations Group,  
Kashiwa  
2-1, Shintoyofuta,  
Kashiwa-shi, Chiba,  
277-0804 Japan**

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

**See attachments for the scope of certification**

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: 2019-12-27

Certificate Registration No.: SX 60144495 0001

An audit was performed. Report No.: 12031275 009

This Certificate is valid until: 2022-12-26

Certification Body



Date 2019-12-04



**T. Matsuda**  
Takashi Matsuda

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

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

Doc.1/2, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60144495 0001  
**Report No.:** 12031275 009

**Organization:** Hitachi, Ltd.  
Medical System Operations Group,  
Kashiwa  
2-1, Shintoyofuta,  
Kashiwa-shi, Chiba,  
277-0804 Japan

**Scope:** Design and Development, Manufacture and Servicing Support of  
Diagnostic X-ray Equipment, X-ray CT Systems, MRI Systems,  
Ultrasound Diagnostic Systems, Ultrasound Transducer/Probes,  
Optical Encephalography Systems, Blood Irradiators, X-ray  
Tubes, X-ray Tube Assemblies, Diagnostic Image Workstations  
and Surgical Navigation System

**Certification Body**



**Date:** 2019-12-04

  
**Takashi Matsuda**

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

Doc.2/2, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60144495 0001  
**Report No.:** 12031275 009

**Organization:** Hitachi, Ltd.  
Medical System Operations Group,  
Kashiwa  
2-1, Shintoyofuta,  
Kashiwa-shi, Chiba,  
277-0804 Japan

**Scope:** Sites included:

Hitachi Healthcare Manufacturing, Ltd. Kashiwa Factory  
2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan  
3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan

Scope:  
Manufacture of Diagnostic X-ray Equipment, X-ray CT Systems,  
MRI Systems, Ultrasound Diagnostic Systems, Ultrasound  
Transducer/Probes, Optical Encephalography Systems, Blood  
Irradiators, Diagnostic Image Workstations and Surgical  
Navigation System

Hitachi Healthcare Manufacturing, Ltd. Mobara Branch Factory  
1754, Sangaya, Mobara-shi, Chiba, 297-0042, Japan

Scope:  
Design, Development and Manufacture of X-ray Tubes and  
X-ray Tube Assemblies

**Certification Body**



**Date:** 2019-12-04

  
**Takashi Matsuda**