

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




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