

TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 095005 0031 Rev. 01

Manufacturer: **Hitachi, Ltd.**
2-16-1, Higashi-Ueno, Taito-ku
Tokyo
110-0015 JAPAN

Product Category(ies): **Diagnostic Ultrasound Systems,
related Probes and Their Accessories**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235039329**

Valid from: **2020-01-10**
Valid until: **2024-05-26**

Date, **2020-01-10**

Christoph Dicks
Head of Certification/Notified Body



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Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 095005 0031 Rev. 01

Facility(ies):

Hitachi, Ltd.
 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015 JAPAN

Hitachi, Ltd. Healthcare Ultrasound R&D Center
 3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014
 JAPAN

Hitachi, Ltd. Healthcare Mitaka Works
 6-22-1, Mure, Mitaka-shi, Tokyo, 181-8622 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Tokyo Works
 3-7-19, Imai, Ome-shi, Tokyo, 198-8577 JAPAN

Hitachi Healthcare Manufacturing, Ltd.
Analytical Systems Kashiwa Factory
 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

Hitachi Healthcare Manufacturing, Ltd.
Analytical Systems Kashiwa Factory
 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

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

-/-

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

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**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. Mobarra Branch Factory
1754, Sangaya, Mobarra-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

March 30, 2021

Subject: Notification of changes due to company name change

1. Background

Based on “Hitachi Announces the Conclusion of Absorption-type Company Split Agreement Relating to Diagnostic Imaging-related Business”, issued on February 18, 2021 (hereinafter referred to as “Hitachi News Release Feb 18, 2021”), Hitachi, Ltd. will execute an absorption-type split and its Healthcare Business Unit’s diagnostic imaging business (CT, MRI, X-ray diagnostic equipment, ultrasound diagnostic imaging equipment, etc.) will be absorbed and split into a newly established company. Based on the absorption-type split, the new company name will change to FUJIFILM Healthcare Corporation.

After the transfer of shares of FUJIFILM Healthcare Corporation, a subsidiary of Hitachi, Ltd., to FUJIFILM Corporation on March 31, 2021, FUJIFILM Corporation will become a shareholder of FUJIFILM Healthcare Corporation, and FUJIFILM Healthcare Corporation will become a subsidiary of FUJIFILM Corporation. Since Hitachi, Ltd. and FUJIFILM Corporation are separate companies that have no capital relationship, Hitachi, Ltd. and FUJIFILM Healthcare Corporation will also be separate companies that have no capital relationship on March 31, 2021.

More information is available on the attached sheet, titled “Hitachi News Release Feb 18, 2021.”

2. Company name change overview

The table below shows the transition of changes in the shareholders of legal manufacturers, exporters, and sales companies in order to conduct manufacturing registrations and product registrations in each country.

Content	Before March 31, 2021	March 31, 2021~ June 30, 2021	After July 1, 2021
Legal manufacturer Name	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare Corporation (*1)
Brand name	HITACHI	HITACHI	FUJIFILM

©Hitachi, Ltd. Healthcare Business Unit

Ueno East Tower, 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan
Tel.:+81-3-6284-3800 <http://www.hitachi.com/businesses/healthcare/>

Content	Before March 31, 2021	March 31, 2021~ June 30, 2021	After July 1, 2021
Exporter	Hitachi, Ltd.	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation
Sales Company	Hitachi, Ltd.	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation
Shareholder of Sales Company	Hitachi, Ltd.	FUJIFILM Corporation	FUJIFILM Corporation
ISO13485 holder	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare Corporation
Company name listed in FSC (Free Sales Certificate)	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare Corporation

(*1) However, when shipping products under the new brand, administrative procedures in each country are required because the products can only be shipped after the product registration, which specifies the change in legal manufacturer and address, is completed.

Even after the change of legal manufacturer, the manufacturing process, quality management system (QMS) and product safety of the product will remain unchanged, with no impact on the factory and QMS.

Responsibility for sold HITACHI brand products and HITACHI brand inventory will be transferred to FUJIFILM Healthcare Corporation.

3. Changes regarding global subsidiaries

Following the absorption-type split of the diagnostic imaging business (CT, MRI, X-ray diagnostic equipment, ultrasound diagnostic imaging equipment, etc.) of Hitachi, Ltd. Healthcare Business Unit and the transfer of shares of the new company, the shareholders and company name of the global subsidiaries will also be changed and incorporate FUJIFILM Healthcare Corporation.

Hitachi, Ltd.

Akio Yamamoto

Name: Akio Yamamoto

Title: CEO

Healthcare Business Unit



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