Business Stream Products
Certification Department

TÜVRheinland®
LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

FUJIFILM Healthcare Corporation
2-1, Shintoyofuta, Kashiwa-shi,
Chiba, 277-0804 JAPAN

Contact
Michiaki Aihara

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date October 27, 2021

Application for: QMS
Certificate No. : HD 1563446-1
Requirement : Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Confirmation letter ID : 2021-06-30
Report no. : 150243980-303

To whom it may concern

Update of information to Certificate no. HD 1563446-1, issued on 2021-03-18

The change notification received on 2021-04-07 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised European Authorized Representative name

Old name: Hitachi Medical Systems GmbH

New name: FUJIFILM Healthcare Deutschland GmbH

Address: Otto-von-Guericke-Ring 3, D-65205 Wiesbaden, Germany

Best regards,

X Aihara

Michiaki Aihara

Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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

Contact
Michiaki Aihara

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date June 30, 2021

Application for: QMS
Certificate No. : HD 1563446-1
Requirement : Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Confirmation letter ID : 2021-06-30
Report no. : 150243980-303

To whom it may concern

Update of information to Certificate no. HD 1563446-1, issued on 2021-03-18

The change notification received on 2021-04-28 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer name

Old Manufacturer name: Hitachi, Ltd.

New Manufacturer name: FUJIFILM Healthcare Corporation

Revised Manufacturer address

Old Manufacturer address:

2-16-1, Higashi-Ueno, Taito-ku, Tokyo 110-0015 Japan

New Manufacturer address:

2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

Revised location name and address

Old location name</02>: Hitachi, Ltd. Healthcare Ultrasound R&D Center

New location name</02>: FUJIFILM Healthcare Corporation Healthcare Ultrasound R&D Center

Address</02>: 3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014 Japan

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www.tuv.com/safety

Revised location name and address

Old location name</03>: Hitachi, Ltd. Medical System Operations Group ,Kashiwa

New location name</03>: FUJIFILM Healthcare Corporation Medical System Operations Group, Kashiwa

Address</03>: 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Old location name</04>: Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory

New location name</04>: FUJIFILM Healthcare Manufacturing Corporation Analytical Systems Kashiwa Factory

Address</04>: 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Old location name</05>: Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory

New location name</05>: FUJIFILM Healthcare Manufacturing Corporation Analytical Systems Kashiwa Factory

Address</05>: 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Deleted location name and address

Old location </01>: Hitachi, Ltd. Healthcare Mitaka Works
6-22-1 Mure Mitaka-shi, Tokyo 181-8622 Japan

Best regards,

X Aihara

Michiaki Aihara

Certification body

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1563446-1

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

Products: Diagnostic Ultrasound Systems, related Probes and Their Accessories

For the following medical device the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterilized puncture adapter

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.

Report No.: 150232389-210

Effective date: 2021-03-18

Expiry date: 2024-05-26

Issue date: 2021-03-18

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierung

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1563446-1

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

No.	Location	Product groups manufactured
/01	Hitachi, Ltd. Healthcare Mitaka Works 6-22-1 Mure Mitaka-shi, Tokyo, 181-8622 Japan	Diagnostic Ultrasound Systems, related Probes and Their Accessories Sterilized puncture adapter
/02	Hitachi, Ltd. Healthcare Ultrasound R&D Center 3-1-1, Higashikoigakubo Kokubunji-shi, Tokyo, 185-0014 Japan	Diagnostic Ultrasound Systems, related Probes and Their Accessories Sterilized puncture adapter
/03	Hitachi, Ltd. Medical System Operation Group, Kashiwa 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan	Diagnostic Ultrasound Systems, related Probes and Their Accessories Sterilized puncture adapter

Report No.: 150232389-210

Effective date: 2021-03-18

Expiry date: 2024-05-26

Issue date: 2021-03-18

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EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1563446-1

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

/04	Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory 2-1 Shintoyofuta Kashiwa-shi, Chiba, 277-0804 Japan	Diagnostic Ultrasound Systems, related Probes and Their Accessories Sterilized puncture adapter
/05	Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan	Diagnostic Ultrasound Systems, related Probes and Their Accessories Sterilized puncture adapter

Report No.: 150232389-210

Effective date: 2021-03-18

Expiry date: 2024-05-26

Issue date: 2021-03-18

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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