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 Zertifizierung TÜVRheinland

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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

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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

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