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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Digitally signed by Grabazei Alexandru
Date: 2023.11.08 09:42:43 EET
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT ◆ ZERTIFIKAT

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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

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
A4 / 07.17