ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 01 95005 020

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

EC-Representative:
Hitachi Medical Systems GmbH
Otto-von-Guericke-Ring 3
65205 Wiesbaden
GERMANY

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.: JAQ235027675

Valid from: 2017-02-21
Valid until: 2020-01-10

Digitally signed by Grabazei Alexandru
Date: 2019.04.01 19:51:26 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2017-02-21

Stefan Preiß

Digitally signed by Grabazei Alexandru
Date: 2019.04.10 09:30:57 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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 17 01 95005 020

Facility(ies):

Hitachi, Ltd. Healthcare Business Unit
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 Ome Logistics Center
1-4-1, Suehiro-cho, Ome-shi, Tokyo, 198-0025 JAPAN

Hitachi, Ltd. Healthcare Analytical Equipment Center
3-4-22, Imai, Ome-shi, Tokyo, 198-0023 JAPAN

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

Hitachi Healthcare Manufacturing, Ltd. Ome Logistics Center
1-4-1, Suehiro-cho, Ome-shi, Tokyo, 198-0025 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Analytical Equipment Center
3-4-22, Imai, Ome-shi, Tokyo, 198-0023 JAPAN