



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:**

**2021-01-10**



**Date, 2017-02-21**

*S. Preis*

Stefan Preis

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

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#### NOTARIAL CERTIFICATE

#### 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

