DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 095005 0030 Rev. 00

Holder of Certificate: **Hitachi, Ltd.**
2-16-1, Higashi-Ueno, Taito-ku
Tokyo
110-0015 JAPAN

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, and Distribution of Instruments, Systems and Accessories for the following Applications: Diagnostic Ultrasound, Bone Densitometry, Clinical Laboratory Test, Automated Pipetting, Luminometry & Photometry and Sterilized puncture adaptor**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: **JAQ235034769**

Valid from: **2019-03-11**
Valid until: **2021-03-31**

Date, **2019-03-11**

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Digitally signed by Grabazei Alexandru
Date: 2020.06.04 14:47:24 EEST
Reason: MoldSign Signature
Location: Moldova

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

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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