



America

CERTIFICATE

No. QS6 035989 0070 Rev. 02

Certificate Holder:**TANITA Corporation**1-14-2, Maeno-cho, Itabashi-ku
Tokyo
174-8630 JAPAN**Certification Mark:****Scope of Certificate:**

Design and Development, Manufacturing, Distribution and Servicing of Medical Weighing Equipment, Medical Scale for Pediatric / Neonatal Use, Body Composition Analyzer, and Medical Sensor for Sleep Monitoring; Manufacturing, Distribution and Servicing of Blood Pressure Monitor, Clinical Electronic Thermometer, Ultrasonic Bone Density Measuring Device

Standard(s):**ISO 13485:2016****Regulatory Authority(ies):****Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:**F001357****Effective Date:****2021-07-17****Expiry Date:****2024-07-16**

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(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

TANITA Corporation
1-14-2, Maeno-cho, Itabashi-ku, Tokyo, 174-8630 JAPAN

TANITA Corporation of AKITA LTD.
28-1, Aza-Shimotamogizoe, Horiminai, Daisen-shi, Akita, 014-0113 JAPAN

Facility Scopes:


TANITA Corporation

1-14-2, Maeno-cho, Itabashi-ku, Tokyo, 174-8630, JAPAN

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REPs Facility ID: F002254

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