



America

CERTIFICATE

No. QS6 012163 0076 Rev. 02

Certificate Holder:

seca

seca gmbh & co. kg
 Hammer Steindamm 3-25
 22089 Hamburg
 GERMANY

Certification Mark:



Scope of Certificate:

**Design and Development, Production,
 Distribution and Service of Medical Scales,
 Software and Medical Devices for Monitoring
 Vital and Non-Vital Physiological Parameters**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, 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:

F001724

Effective Date:

2021-12-11

Expiry Date:

2024-12-10

Page 1 of 2

Date of Issue: 2021-12-10

(Michael Ogunleye)
 Manager, US Certification Body,
 Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

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

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Page 2 of 2

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