



CERTIFICATE

No. QS6 012163 0076 Rev. 04

Certificate Holder: **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 Measuring Vital and Non-Vital Physiological Parameters**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 012163 0076 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:QS6_012163_0076_Rev.04)

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

REPs Facility ID: **F001724**
Report No.: **713318652**
Effective Date: **2024-09-15**
Expiry Date: **2027-09-14**

Page 1 of 2

Date of Issue: 2024-07-30

(Renee Walker)
Director, US Certification Body, MHS

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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 No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

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

Facility(ies):

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Facility Scopes:

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Page 2 of 2

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