MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 012163 0076 Rev. 00

Certificate Holder: seca

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

Certification Mark:

TÜV SÜD ISO 13485

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, Brazil ANVISA, 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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **31-658-4937**

Effective Date: **2018-12-11**

Expiry Date: **2021-12-10**

Date of Issue: 2018-12-26

(Arie Henkin)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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US-Letter / 07.17

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Regulatory Requirements:	Audit/Certification Criteria
	Australia Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1
	Brazil - RDC ANVISA n. 16/2013 - RDC ANVISA n. 23/2012 - RDC ANVISA n. 67/2009
	Canada - Medical Device Regulations SOR/98-282, Part 1
	United States - 21 CFR Part 803 - 21 CFR Part 806 - 21 CFR Part 807 - 21 CFR Part 820
	Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68 - PMD Act
Facility(ies):	seca gmbh & co. kg Hammer Steindamm 3-25, 22089 Hamburg, GERMANY
Facility Scopes:	Design and Development, Production, Distribution and Service of Medical Scales, Software and Medical Devices for Monitoring Vital and Non-Vital Physiological Parameters DUNS No: 31-658-4937

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