



America

CERTIFICATE

No. QS6 021697 0022 Rev. 02

Certificate Holder:

Honeywell Healthcare Solutions GmbH
Alter Holzhafen 18
23966 Wismar
GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Service and Distribution of Sensors and Control Units for Monitoring of Vital Physiological Parameters, Sensors and Control Units for Monitoring of Respiratory Mechanics Parameters and Gas Exchange

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_021697_0022_Rev.02

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

REPs Facility ID:

F001223

Report No.:

713300514

Effective Date:

2024-01-26

Expiry Date:

2027-01-25

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Date of Issue: 2024-01-26

(Renee Walker)

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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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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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