ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 021697 0022 Rev. 01

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, 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: **F001223**

Effective Date: **2022-02-17**

Expiry Date: **2024-01-28**

Date of Issue: 2022-02-28

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

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 021697 0022 Rev. 01

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

Facility(ies): Honeywell Healthcare Solutions GmbH
Alter Holzhafen 18, 23966 Wismar, GERMANY

Facility Scopes: 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
REPs Facility ID: F001223

Date of Issue: 2022-02-28

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

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com