MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD
America

CERTIFICATE

No. QS6 049861 0155 Rev. 00

Certificate Holder: **ResMed Limited**
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and Distribution, Installation and Service of Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes, Ventilator Software, Batteries, Alarms, Trollies, Bags, Covers, Restraints, Pressure Alleviation Pads, Cleaning Wipes and Patient Data Recorders (Respiratory)**

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: **75-114-9311**

Effective Date: **2018-12-13**

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

Date of Issue: 2018-12-13

(Arie Henkin)
Manager, Certification Body MHS

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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
- 21 CFR Part 821

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies): ResMed Limited
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153,
AUSTRALIA

Facility Scopes: Design and Development, Manufacture and Distribution, Installation and Service of Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes, Ventilator Software, Batteries, Alarms, Trollies, Bags, Covers, Restraints, Pressure Alleviation Pads, Cleaning Wipes and Patient Data Recorders (Respiratory)
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TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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