



Benannt durch Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 049861 0162 Rev. 04

Manufacturer:

ResMed Pty Ltd

1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

SRN Manufacturer - AU-MF-000011753

Authorized Representative:

ResMed SAS

Parc Technologique de Lyon, 292 Allée Jacques Monod, 69791
Saint-Priest Cedex, FRANCE

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 049861 0162 Rev. 04

Report No.:

JA200350004813

Preceding Certificate No.:

G10 049861 0162 Rev. 03

Valid from:

2024-12-09

Valid until:

2025-10-06

Date of Initial Issuance:

2020-10-07

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2024-12-09



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| | |
|--------------------------|--|
| Classification: | Class IIa |
| Device Group: | R020107 - THERMOREGULATED BREATHING CIRCUITS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R020104 - CPAP AND NIV BREATHING CIRCUITS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R030101 - VENTILATION MASKS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R0203 - ANAESTHESIA AND RESUSCITATION CONNECTORS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R0280 - BREATHING CIRCUITS AND CATHETER MOUNTS - ACCESSORIES |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS |
| Intended Purpose: | -/- |
| Classification: | Class IIa |
| Device Group: | R040199 - VENTILATION FILTERS - OTHER |
| Intended Purpose: | -/- |
| Classification: | Class IIb |
| Device Group: | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| Intended Purpose: | To provide continuous or intermittent ventilatory support for patients requiring non-invasive or invasive ventilation |



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No. G10 049861 0162 Rev. 04

Classification: Class IIa
Device Group: Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose: -/-

The validity of this certificate -/-
depends on conditions and/or
is limited to the following:

Revision History:

| Rev. | Dated | Report | Description |
|------|------------|----------------|--|
| 00 | 2020-10-07 | JA1437662 | - |
| 01 | 2022-02-10 | JA1634396 | - |
| 02 | 2022-08-04 | JA36117609 | - |
| 03 | 2024-10-02 | JA36068807 | Supplemented: Device(s)/group of device(s) added |
| 04 | 2024-12-09 | JA200350004813 | Supplemented: Device(s)/group of device(s) added |



Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

Authorized Representative:

ResMed SAS
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint Priest Cedex
France

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product: AirSense 10 Elite

Intended Use:

The AirSense 10 Elite device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

Classification: IIa according to Rule 9

EMDN: Z12030102 Continuous Positive Pressure Equipment

Conformity Assessment Route: Annex IX (excluding Chapter II), Regulation EU 2017/745

Basic UDI-DI: 619498EC1496T

Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2014/53/EU and Machinery Directive 2006/42/EEC.

Compliance is applicable from the date listed below. All supporting documentation is retained at the premises of the manufacturer. This declaration is issued under the sole responsibility of ResMed Pty. Ltd.

EC Certificate Number: G10 049861 0162 Rev. 04

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 17 December 2024

DocuSigned by:

Nicole Wilson

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Nicole Wilson
Person Responsible for Regulatory Compliance (PRRC)
ResMed Pty. Ltd.

EC149.3

First issued: 11 December 2021