



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



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(Class IIa and Class IIb Devices)

**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:	Authorized Representative:	Notified Body:
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

**Product:** AirFit P10 and AirFit P10 For Her

## Intended Use:

The AirFit P10 / AirFit P10 For Her channel airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.

The AirFit P10 / AirFit P10 For Her is:

- to be used by patients >30 kg (66lbs) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment

**Classification:** IIa according to Rule 2

**EMDN:** R0301010201 CPAP Masks

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

**Basic UDI-DI:** 619498EC1426D

**Common Specification:** N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices.

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.

**EC142.1**

First issued: 05 April 2022