



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

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**Manufacturer:**

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

**Authorised 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

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**Product:**

AirFit N20 and AirFit N20 For Her

**Intended Use:**

The Air Fit N20 / Air Fit N20 For Her Nasal Mask System is a non-invasive accessory used for channelling air-flow to a patient from a positive airway pressure device such as Continuous Positive Airway Pressure (CPAP) or bilevel system.

The Air Fit N20 / Air Fit N20 For Her Nasal Mask System is:

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

**Classification:**

Ila according to Rule 2

**GMDN:**

57815 CPAP/BPAP nasal mask, reusable

**Conformity Assessment Route:** Annex II (excluding Section 4), 93/42/EEC

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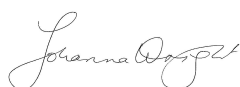
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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:** G1 049861 0158

Signed at Sydney, Australia on: 11 December 2019



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Johanna Wright  
Director of Regulatory Affairs  
ResMed Pty. Ltd.

**EC173a**

First issued: 2 November 2016