



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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No. G10 049861 0162 Rev. 04

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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(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:

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

Product: Mirage FX and Mirage FX For Her

Intended Use:

The Mirage FX and Mirage FX For Her channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device. The Mirage FX and Mirage FX For Her are:

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

Classification: IIa according to Rule 2

GMDN: 57815 CPAP/BPAP nasal mask, reusable

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

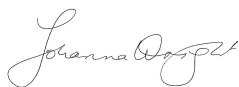
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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



Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.