



Declaration of Conformity

Manufacturer: Authorised Representative: Notified Body:

ResMed Pty. Ltd. ResMed SAS

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TÜV SÜD Product Service

GmbH

Ridlerstraße 65 80339 München

Germany

Product: Mirage Micro

Intended Use: The Mirage Micro channels airflow noninvasively to a patient from a positive airway

pressure device such as a continuous positive airway pressure (CPAP) or bi-level

system. The Mirage Micro is:

• to be used by adult patients (>30 kg) 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

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.