

Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
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Bella Vista
NSW 2153
Australia

Authorised Representative:

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292 Allée Jacques Monod
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France

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product: AirFit F10 and AirFit F10 For Her

Intended Use: The Air Fit F10 / Air Fit F10 For Her Mask System is a non-invasive accessory used for channelling air-flow (with or without supplemental oxygen) to a patient from a positive airway pressure device such as Continuous Positive Airway Pressure (CPAP) or bilevel system.

The Air Fit F10 / Air Fit F10 For Her 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: IIa according to Rule 2

GMDN: 57814 CPAP/BPAP face mask, reusable

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

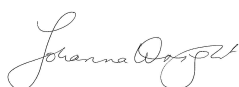
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

EC141

First issued: 24 February 2014