

## Declaration of Conformity

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**Manufacturer:**

ResMed Pty. Ltd.  
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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 F20 and AirFit F20 For Her

**Intended Use:** The AirFit F20 / AirFit F20 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 AirFit F20 / AirFit F20 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

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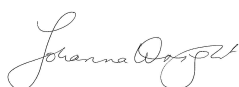
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

**EC172a**

First issued: 24 October 2016