RESMED

Declaration of Conformity

CE 0123

Manufacturer:	European Representative:	Notified Body:
ResMed Ltd	***ResMed (UK) Ltd***	***TÜV SÜD Product Service GmbH***
1 Elizabeth Macarthur Drive	96 Jubilee Ave, Milton Park	Ridlerstraße 65
Bella Vista	Abingdon	80339 München
NSW 2153	Oxfordshire OX14 4RY	Germany
Australia	United Kingdom	

Product: **Air Fit F20 / Air Fit F20 for Her**

The Air Fit F20 / Air Fit 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 Air Fit F20 / Air Fit 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.

Standards Applied: EN ISO 10993-1:2009
EN ISO 17510:2015
EN ISO 5356-1:2004 (sections 5.1 & 5.2)
EN ISO 17664:2004
EN ISO 14971:2012
EN 980:2008
EN 62366-1:2015

Classification: IIa (according to Rule 2)

GMDN: 35171 - Mask Air, oxygen.

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

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of Council Directive 93/42/EEC including the MDD amendment (2007/47/EC), for medical devices. Compliance to the MDD and the standards referenced above 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 Ltd.

EC Certificate number: G1 16 06 49861 115

Signed at Sydney, Australia on: .....**24 October 2016**.....

Johanna Wright
Director, Regulatory Affairs
ResMed Ltd