RESMED

CE 0123

Declaration of Conformity

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

Product: **AirFit**™ P10 & **AirFit**™ P10 for Her

The **AirFit**™ P10 / **AirFit**™ P10 for her channel airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.
The **AirFit**™ P10 / **AirFit**™ P10 for Her is:

- to be used by patients >30 kg (66lbs) 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

Standards Applied: EN ISO 14971: 2012
EN ISO 10993-1:2009
EN ISO 17510-2:2009
EN ISO 5356-1:2004 (sections 5.1 & 5.2)
EN ISO 15223-1:2007
EN 980:2008

Classification: IIa (according to Rule2)

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.

EC Certificate number G1 12 05 49861 017

Signed at Sydney, Australia on: .....***31 October 2013***.....

Dr. Simon Lewi
Director – Regulatory Affairs
ResMed Ltd