ResMed

CE 0123

Declaration of Conformity

Manufacturer:	**Authorised Representative:**	**Notified Body:**
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: AirFit P10 and AirFit P10 For Her

Intended Use: 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

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.

EC142

First issued: 30 October 2013