ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorised Representative:	Notified Body:
ResMed 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 P30i

Intended Use: The AirFit P30i mask is intended to be used by patients weighing more than 30 kg who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multi-patient 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 Ltd.

EC Certificate Number: G1 17 08 49861 149

Signed at Sydney, Australia on: 04-Feb-19

Johanna Wright
Director of Regulatory Affairs
ResMed Ltd.

EC181b

First issued: 06-Feb-19