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 N30 for AirMini

Intended Use: The AirFit N30 for AirMini Mask System is an accessory that is used for channeling airflow to a patient non-invasively. It has custom connecting ports to ensure that it can only be connected to compatible ResMed CPAP devices.
The AirFit N30 for AirMini mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP therapy. It is intended for single patient re-use in the home and 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: 27 April 2020

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC187

First issued: 27 April 2020