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 N20 and AirFit N20 For Her

Intended Use: The Air Fit N20 / Air Fit N20 For Her Nasal Mask System is a non-invasive accessory used for channelling air-flow to a patient from a positive airway pressure device such as Continuous Positive Airway Pressure (CPAP) or bilevel system.

The Air Fit N20 / Air Fit N20 For Her Nasal 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.

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.

EC173a

First issued: 2 November 2016