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: ApneaLink Air

Intended Use: The ApneaLink Air device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Air records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse and respiratory effort during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.

Classification: IIa according to Rule 10

GMDN: 33843 Polysomnograph

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: 10 August 2021

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC148

First issued: 4 May 2017