

Declaration of Conformity

Manufacturer:

ResMed Pty Ltd.
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Bella Vista
NSW 2153
Australia

Authorised Representative:

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292 Allée Jacques Monod
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France

Notified Body:

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

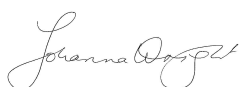
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC

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