ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorized 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: AirMini

Intended Use:
The AirMini self-adjusting system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended for home and hospital use.

Classification: IIa according to Rule 9

GMDN: 60711 Home CPAP unit

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, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2014/53/EU, and Machinery Directive 2006/42/EEC.

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: 19 January 2023

DocuSigned by:
Nicole Wilson
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Nicole Wilson
Director Global Product Regulatory Affairs
ResMed Pty. Ltd.

EC174.1
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