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: Remote Alarm II

Intended Use: The Remote Alarm is intended for home and hospital use. Its primary purpose is to alert the caregiver of a ventilation patient to an alarm condition on the ventilator even when the caregiver is not at the bedside or in the same room with the patient and ventilator.

The Remote Alarm generates an audible and visual signal when an alarm is triggered on the ventilator. The Remote Alarm is powered by battery and connected to the ventilator via a cable.

Classification: IIb according to Rule 9

GMDN: 35426 Airway pressure alarm

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.

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.

EC133

First issued: 28 November 2012