

Declaration of Conformity

Manufacturer:

ResMed Ltd.
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Bella Vista
NSW 2153
Australia

Authorised Representative:

ResMed SAS
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint Priest Cedex
France

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product: Astral 100, 100 SC and 150 (Germany)

Intended Use:

The Astral device provides continuous or intermittent ventilatory support for patients weighing more than 5 kg who require mechanical ventilation. The Astral device is intended to be used in home, institution/hospital and portable applications for both invasive and non-invasive ventilation.

The Astral device is available in three trim levels:

- Astral 100 SC provides intermittent ventilatory support via a single circuit with expiratory valve.
- Astral 100 provides continuous ventilatory support via a single circuit with intentional leak or intermittent ventilatory support via a single circuit with expiratory valve.
- Astral 150 provides continuous ventilatory support via a double or single circuit with intentional leak or intermittent ventilatory support via a single circuit with expiratory valve.

Classification: IIb according to Rule 11

GMDN: 47083 Portable ventilator, electric

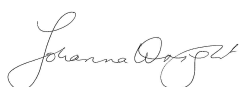
Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

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 Ltd.

EC Certificate Number: G1 17 08 49861 149

Signed at Sydney, Australia on: 14-Aug-18



Johanna Wright
Director of Regulatory Affairs
ResMed Ltd.