ResMed

CE 0123

# Declaration of Conformity

| Manufacturer: | Authorised Representative: | Notified Body: |
|---|---|---|
| ResMed Ltd.<br>1 Elizabeth Macarthur Drive<br>Bella Vista<br>NSW 2153<br>Australia | ResMed SAS<br>Parc Technologique de Lyon<br>292 Allée Jacques Monod<br>69791 Saint Priest Cedex<br>France | TÜV SÜD Product Service GmbH<br>Ridlerstraße 65<br>80339 München<br>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.

EC129

First issued: 08-May-14