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# Declaration of Conformity

| Manufacturer: | Authorized Representative: | Notified Body: |
|---|---|---|
| ResMed Pty. 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:** AirSense 10 AutoSet

**Intended Use:**
The AirSense 10 AutoSet self-adjusting device 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.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

**Classification:** IIa according to Rule 9

**EMDN:** Z12030102 Continuous Positive Pressure Equipment

**Conformity Assessment Route:** Annex IX (excluding Chapter II), Regulation EU 2017/745

**Basic UDI-DI:** 619498EC1496T

**Common Specification:** N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices, 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.

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:** G10 049861 0162 Rev. 02

**SRN:** AU-MF-000011753

Signed at Sydney, Australia on: 23 August 2022

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

EC149.1
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