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## Declaration of Conformity

**Manufacturer:**

ResMed Pty. Ltd.  
1 Elizabeth Macarthur Drive  
Bella Vista  
NSW 2153  
Australia

**Authorized 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:** 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, 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:** G15 049861 0261 Rev. 00

**SRN:** AU-MF-000011753

Signed at Sydney, Australia on: 30 June 2025

DocuSigned by:

*Nicole Wilson*

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Nicole Wilson  
Person Responsible for Regulatory Compliance (PRRC)  
ResMed Pty. Ltd.

# EC149.1

First issued: 11 December 2021