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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:** AirFit P10 and AirFit P10 For Her

**Intended Use:**

The AirFit P10 / AirFit P10 For Her channel airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.

The AirFit P10 / AirFit P10 For Her is:

- to be used by patients >30 kg (66lbs) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment

**Classification:** IIa according to Rule 2

**EMDN:** R0301010201 CPAP Masks

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

**Basic UDI-DI:** 619498EC1426D

**Common Specification:** N/A

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

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.

# EC142.1

First issued: 05 April 2022