Resmed

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Declaration of Conformity

Manufacturer:	Authorized Representative:	Notified Body:
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	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. 01

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 20 April 2026

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

EC142.1
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