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: AirCurve 11 ASV PaceWave

Intended Use:
The AirCurve 11 ASV PaceWave system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 30kg. ASV and ASVAuto modes are also indicated for the treatment of central and/or mixed apneas, or periodic breathing. The AirCurve 11 ASV PaceWave system is intended for use in the hospital and home.

Classification: IIa according to Rule 12

EMDN: Z12030102 Continuous Positive Pressure Equipment

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

Basic UDI-DI: 619498EC1997A

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.

EC199.1
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