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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: AirCurve 11 ST

Intended Use:

The AirCurve 11 ST system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 13kg. The AirCurve 11 ST system is intended for use in the hospital and home.

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: 619498EC19878

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.

EC198.2

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