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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 10 CS-A Pacewave

Intended Use:
The AirCurve 10 CS-A PaceWave is indicated to stabilise the ventilation of adult patients exhibiting central sleep apnoea (CSA), mixed sleep apnoea and periodic breathing, with or without obstructive sleep apnoea. 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 12

CND: Z12030103 Extra hospital portable ventilators

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

Basic UDI-DI: 619498EC1776Y

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 and Directive 2014/53/EU.

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: G10 049861 0162 Rev. 01

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 22 February 2022

Daniel Judson
Vice President of Global Product Quality Assurance
ResMed Pty. Ltd.