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Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
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Bella Vista
NSW 2153
Australia

Authorized Representative:

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292 Allée Jacques Monod
69791 Saint Priest Cedex
France

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product: AirCurve 10 VAuto

Intended Use:

The AirCurve 10 VAuto device is indicated for the treatment of Obstructive Sleep Apnea in patients weighing (more than 66lb / 30 kg) and (more than 30lb / 13 kg in CPAP and S modes). 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 9

CND: Z12030102 Continuous Positive Airway Pressure units (CPAP)

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

Basic UDI-DI: 619498EC1506C

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.

EC150.3

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