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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: AirSense 11 Elite

Intended Use:
The AirSense 11 Elite system is indicated for the treatment of obstructive sleep apnoea (OSA) in patients weighing more than 30 kg. The AirSense 11 Elite system is intended for home and hospital use.

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: 619498EC19776

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: 14 April 2022

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

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