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CE 0123

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: AirTouch F20 and AirTouch F20 For Her

Intended Use:
The AirTouch F20 / AirTouch F20 For Her Mask System is a non-invasive accessory used for channelling air-flow (with or without supplemental oxygen) to a patient from a positive airway pressure device such as Continuous Positive Airway Pressure (CPAP) or bilevel system.
The AirTouch F20 / AirTouch F20 For Her Mask System is:
• to be used by patients (weighing >66 lb/30 kg) for whom positive airway pressure therapy has been prescribed.
• intended for single patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment.

Classification: IIa according to Rule 2

EMDN: R0301010201 CPAP Masks

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

Basic UDI-DI: 619498EC1726N

Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices.

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. 02

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 29 June 2023

DocuSigned by:
Nicole Wilson
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Nicole Wilson
Person Responsible for Regulatory Compliance (PRRC)
ResMed Pty. Ltd.

EC172b.1
First issued: 11 March 2022