ResMed

CE 0123

Declaration of Conformity

Manufacturer:	Authorised 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: AcuCare F1-0

Intended Use: The AcuCare F1-0 mask is a non-invasive accessory used for channeling airflow to a patient from an active-exhaust-valve ventilator system. The mask is:
• to be used on patients weighing >66 lb (30 kg), for whom non-invasive positive airway pressure therapy has been prescribed.
• a disposable device, intended for short-term treatment (up to 7 days) of a single patient, in the hospital environment only.
• intended to be used with breathing circuits or positive pressure ventilation (PPV) devices that provide their own method of venting expired or supplemental gasses.

Classification: IIa according to Rule 2

GMDN: 57813 CPAP/BPAP face mask, single use

Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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: G1 049861 0158

Signed at Sydney, Australia on: 18 June 2021

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.