

## Declaration of Conformity

---

**Manufacturer:**

ResMed Pty. Ltd.  
1 Elizabeth Macarthur Drive  
Bella Vista  
NSW 2153  
Australia

**Authorised Representative:**

ResMed SAS  
Parc Technologique de Lyon  
292 Allée Jacques Monod  
69791 Saint Priest Cedex  
France

**Notified Body:**

TÜV SÜD Product Service  
GmbH  
Ridlerstraße 65  
80339 München  
Germany

---

**Product:** AcuCare F1-4

**Intended Use:**

The AcuCare F1-4 mask is a non-invasive accessory used for channelling airflow to a patient from a positive airway pressure (PAP) device.

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.

**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

---

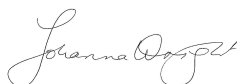
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

**EC159b**

First issued: 3 March 2015