



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: Reusable Breathing Tube

Intended Use: The Reusable Air Tube is a non-invasive accessory used for conveying the air-flow

(with or without supplemental oxygen) generated by flow generators to a face mask or

nasal pillow-system for the treatment of CPAP or Bi-level therapy.

Classification: IIa according to Rule 2

GMDN: 37705 Breathing circuit, ventilator, reusable

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: 11 December 2019

Johanna Wright

Director of Regulatory Affairs

ResMed Pty. Ltd.

EC074

First issued: 6 March 2009