



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

Product: Chin Restraint

Intended Use: The intent of the Chin Restraint is to restrict the mouth from opening during Positive Airway Pressure (PAP) treatment and minimise air loss through the mouth. It can be used in conjunction with a wide range of mask and pillow systems.

Classification: I according to Rule 1

GMDN: 41067 Orthodontic chin cap

Conformity Assessment Route: Annex VII, 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.

Signed at Sydney, Australia on: 11 December 2019

A handwritten signature in black ink, appearing to read "Johanna Wright".

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC116

First issued: 26 July 2011