



Declaration of Conformity

Manufacturer:

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

Authorized 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

EMDN: R030180 Respiratory Masks - Accessories Not Included in Other Classes

Conformity Assessment Route: Annex II and III, Regulation EU 2017/745

Basic UDI-DI: 619498EC1166C

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.

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.

EC116.1

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