

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: Hospital Nasal Mask

Intended Use: The Hospital Nasal Mask is intended for use in adult patients (> 30kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy in hospital and clinic environments. This is a disposable mask intended to be used for the short term (7 days maximum) treatment of single patient only and then discarded.

Classification: IIa according to Rule 2

GMDN: 37591 CPAP/BiPAP nasal mask, single-use

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

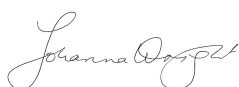
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

EC061

First issued: 10 June 2005