ResMed

CE 0123

Declaration of Conformity

Manufacturer:	**Authorised Representative:**	**Notified Body:**
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	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.

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First issued: 10 June 2005