



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

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product: AirTouch N30i

Intended Use:

The AirTouch N30i mask is intended for patients weighing more than 30 kg, who have been prescribed non-invasive CPAP or bi-level positive airway pressure (PAP) therapy. The mask is intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment.

Classification: IIa according to Rule 2

EMDN: R0301010201 CPAP Masks

Conformity Assessment Route: Annex IX (excluding Chapter II), Regulation EU 2017/745

Basic UDI-DI: 619498EC1816P

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.

EC Certificate Number: G10 049861 0162 Rev. 03

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 20 November 2024

DocuSigned by:

Nicole Wilson

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Nicole Wilson
Person Responsible for Regulatory Compliance (PRRC)
ResMed Pty. Ltd.

EC181c

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