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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: AirFit F30i Non Magnetic

Intended Use:

The AirFit F30i Non Magnetic mask is intended to be used by patients weighing more than 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure (PAP) therapy such as CPAP or bi-level therapy. The mask is intended for single patient re-use in the home and multipatient re-use 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: 619498EC1866Z

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: G15 049861 0261 Rev. 00

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 30 June 2025

DocuSigned by:

Nicole Wilson

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Nicole Wilson

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

EC186c.1

First issued: 12 December 2023