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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

## **Intended Use:**

The AirFit F30i 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 multi-patient re-use in the hospital/institutional environment.

Classification: Ila according to Rule 2

CND: R03010102 BiPAP/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: G10 049861 0162 Rev. 01

**SRN:** AU-MF-000011753

Signed at Sydney, Australia on: 18 March 2022

**Daniel Judson** 

Vice President of Global Product Quality Assurance

ResMed Pty. Ltd.

EC186.1

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