



RED Declaration of Conformity

Manufacturer:

ResMed Pty Ltd 1 Elizabeth Macarthur Drive

Bella Vista NSW 2153 Australia

European Representative:

ResMed SAS

Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex

France

Product Description:

Product Type: AirMini

Trade Name(s): ResMed

Model Number(s): 381XX

Software Version(s): SW1.1.0.131

Accessories: 20W Power supply

Product Characteristics: 2400-2483.5 MHz; EIRP: <10dBm

Channels: 79; Modulation: GFSK, π/4-DQPSK, 8-DPSK

Channels: 40; Modulation: GFSK

Standards Applied:

Health EN 62311:2008

RED, Article 3.1a EN 50566:2013/AC:2014

EN 62209-2:2010

Safety

RED, Article 3.1a

EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013

EMC EN 301 489-1 V2.1.1

RED, Article 3.1b EN 301 489-17 V3.1.1

Radio Spectrum RED, Article 3.2

EN 300 328 V2.1.1

We herewith declare that the product meets national law of the essential requirements. The object of the declaration described above is in conformity with the relevant Union harmonization Legislation: Directive 2014/53/EU (RED).

All the reports of the applied standards have the positive opinion of Notified Body Cetecom with Notified Body number 0682 who issued the EU-type examination certificate.

Note: Any labelling of the product and printed material showing CE 0123, relates the Council Directive 93/42/EEC including the Medical Device Directive 2007/47/EC amendment.

This declaration is issued under the sole responsibility of the ResMed Pty Ltd.

Signed at Sydney, Australia on: 25-Jul-18

Johanna Wright

Director of Regulatory Affairs

ResMed Pty Ltd

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