



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: AirSense 10 Series (4G)

Trade Name(s): ResMed

Model Number(s): 371xx

Software Version(s): Product: SX657-xxxx, Cellular Module: SX558-xxxx

Accessories: ResMed model 370001 and Kingfisher PSU 370006

Product Characteristics: GSM Power class 4 - 900MHz

LTE Power class 3 - Bands 1, 3, 8, 20, 28

GSM Power class 1 - 1800MHz

Standards Applied:

Health EN 50566:2013 RED, Article 3.1a

EN 62209-2:2010

EN 62311:2008

Safety

EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013 RED, Article 3.1a

EMC Draft EN 301 489-1 V2.2.0

RED, Article 3.1b Draft EN 301 489-52 V2.2

Radio Spectrum EN 301 511 V12.5.1 RED, Article 3.2 EN 301 908-13 V11.1.1

EN 301 908-1 V11.1.1

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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