



## **RED Declaration of Conformity**

Manufacturer:

ResMed 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: AirCurve 10 Series (2G)

Trade Name(s): ResMed

Model Number(s): 370xx

Software Version(s): Product: SX567-xxx, Cellular Module: SX558-xxx

Accessories: N/A

Product Characteristics: GSM 900 MHz, 33dBm rated

GSM 1800 MHz, 30dBm rated

Standards Applied:

Health EN 50566:2013

RED, Article 3.1a EN 62209-2:2010

EN 62311:2008

Safety

RED, Article 3.1a

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

EMC Draft EN 301 489-1 V2.2.0

RED, Article 3.1b Draft EN 301 489-52 V1.1

Radio Spectrum EN 301 511 V9.0.2

RED, Article 3.2

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 Telefication B.V. with Notified Body number 0560 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 Ltd.

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

Johanna Wright

**Director of Regulatory Affairs** 

ResMed Ltd.

First issue: 13-Jun-17