



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: Lumis VPAP S and ST Series (4G)
Trade Name(s): ResMed Ltd.
Model Number(s): 285xx
Software Version(s): Product: SX584-xxxx, Cellular Module: SX558-xxxx
Accessories: ResMed model 370001
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
RED, Article 3.1a EN 50566:2013
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
RED, Article 3.1b Draft EN 301 489-1 V2.2.0
Draft EN 301 489-52 V2.2

Radio Spectrum
RED, Article 3.2 EN 301 511 V12.5.1
EN 301 908-13 V11.1.1
EN 301 908-1 V11.1.1

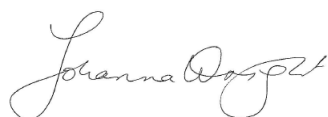
We herewith declare that the product meets national law of the essential requirements. The object of the declaration described above is in conformity with the relevant Union harmonization Legislation: Directive 2014/53/EU (RED).

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 Ltd.

Signed at Sydney, Australia on: 26-Nov-18



Johanna Wright
Director of Regulatory Affairs
ResMed Ltd.

EC161

First issue: 20-Sep-17