



# RED Declaration of Conformity

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**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

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**Product Description:**

**Product Type:** Lumis VPAP S and ST Series (4G)  
**Trade Name(s):** ResMed Pty 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

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**Standards Applied:**

<b>Health</b> <i>RED, Article 3.1a</i>	EN 50566:2013 EN 62209-2:2010 EN 62311:2008
<b>Safety</b> <i>RED, Article 3.1a</i>	EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013
<b>EMC</b> <i>RED, Article 3.1b</i>	Draft EN 301 489-1 V2.2.0 Draft EN 301 489-52 V2.2
<b>Radio Spectrum</b> <i>RED, Article 3.2</i>	EN 301 511 V12.5.1 EN 301 908-13 V11.1.1 EN 301 908-1 V11.1.1

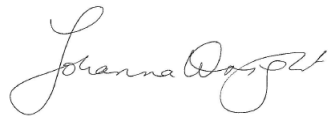
We herewith declare that the product meets national law of the essential requirements. The object of the declaration described above is in conformity with the relevant Union harmonization Legislation: Directive 2014/53/EU (RED).

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 Pty Ltd.

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



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Johanna Wright  
Director of Regulatory Affairs  
ResMed Pty Ltd

EC161

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