



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 / Device Information

Product Type:	Lumis VPAP ST-A Series
Trade Name(s):	ResMed
Model Number(s):	Models 283XX
Software Version(s):	Main Application SX584-xxxx, Cellular Module SX558-xxxx

Supplied Accessories and Components

Adpater	Brand Name: ResMed Model Name: 370001
Air tubing	Brand Name: NA Model Name: NA
SD Card	Brand Name: NA Model Name: NA
HumidAir humidfier	Brand Name: NA Model Name: NA

Standard(s) applied


Health (RED, Article 3.1a)	EN 62311:2008 EN 62209-2:2010 EN 50566 : 2013	Full Compliance
Safety (RED, Article 3.1a)	EN 60950-1:2006+ A11:2009+A1:2010+AC:2011 +A12:2011	Full Compliance
EMC (RED, Article 3.1b)	EN 301 489-1 V2.2.0: (2017-03) EN 301 489-52 V1.1.0 (2016-11)	Full Compliance
Radio spectrum (RED, Article 3.2)	EN 301 511 V9.0.2	Full Compliance

Additional Information

Technical construction file held by:	ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia
Radio Class:	GSM Class 4 GSM 850/900 GSM Class 1 GSM 1800/1900 GSM Class 3 LTE 700, 800, 900, 1100 and 2100

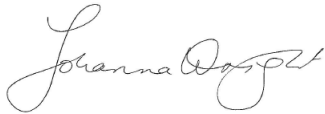
We herewith declare that the product meets national law of the essential requirements. The object of the declaration described above is in conformity with the relevant Union harmonization Legislation: Directive 2014/53/EU (RED).

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  0123, relates the Council Directive 93/42/EEC including the Medical Device Directive amendment (2007/47/EC).

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

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



Johanna Wright
Director of Regulatory Affairs
ResMed Ltd.

EC167

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