CE 0123

Declaration of Conformity

Manufacturer:	Authorized Representative:	Notified Body:
ResMed Pty. Ltd. 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia	ResMed SAS Parc Technologique de Lyon 292 Allée Jacques Monod 69791 Saint Priest Cedex France	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany

Product: Lumis 150 VPAP ST

Intended Use:
The Lumis 150 VPAP ST device is indicated to provide non-invasive ventilation for patients weighing more than 13 kg or more than 30 kg in iVAPS mode with respiratory insufficiency or obstructive sleep apnoea (OSA). It is intended for home and hospital use.

The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

Classification: IIa according to Rule 12

EMDN: Z1203010504 Adult and Paediatric/Neonatal Pulmonary Ventilators

Conformity Assessment Route: Annex IX (excluding Chapter II), Regulation EU 2017/745

Basic UDI-DI: 619498EC1616H

Common Specification: N/A

We herewith declare that the above mentioned products are in conformity with the Council Regulation 2017/745 for medical devices, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2014/53/EU and Machinery Directive 2006/42/EEC.

Compliance is applicable from the date listed below. All supporting documentation is retained at the premises of the manufacturer. This declaration is issued under the sole responsibility of ResMed Pty. Ltd.

EC Certificate Number: G10 049861 0162 Rev. 03

SRN: AU-MF-000011753

Signed at Sydney, Australia on: 20 November 2024

DocuSigned by:
Nicole Wilson
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Nicole Wilson
Person Responsible for Regulatory Compliance (PRRC)
ResMed Pty. Ltd.

EC161.3
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