CE 0123

Declaration of Conformity

Manufacturer:	EU Representative:	Notified Body:
ResMed 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: Swift FX

Intended Use: The Swift FX channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Swift FX is:
• to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed; and
• intended for single-patient re-use in the home and multi-patient re-use in the hospital/institutional environment.

Classification: IIa according to Rule 2

GMDN: 57815 CPAP/BPAP nasal mask, reusable

Conformity Assessment Route: Annex II (excluding Section 4), 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law of the provisions of Council Directive 93/42/EEC including the MDD amendment 2007/47/EC, for medical devices. Compliance to the MDD 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 Ltd.

EC Certificate Number: G1 17 08 49861 149

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

Johanna Wright
Director of Regulatory Affairs
ResMed Ltd