



Declaration of Conformity

Manufacturer:

ResMed Pty. Ltd.
1 Elizabeth Macarthur Drive
Bella Vista
NSW 2153
Australia

Authorised Representative:

ResMed SAS
Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint Priest Cedex
France

Notified Body:

TÜV SÜD Product Service
GmbH
Ridlerstraße 65
80339 München
Germany

Product:

Swift FX For Her

Intended Use:

The Swift FX For Her 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 For Her 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:

Ila 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 are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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: G1 049861 0158

Signed at Sydney, Australia on: 11 December 2019

Johanna Wright
Director of Regulatory Affairs
ResMed Pty. Ltd.

EC107

First issued: 31 January 2011