

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 Nano and Swift FX Nano For Her

Intended Use:

The Swift FX Nano / Swift FX Nano For Her channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device.
The Swift FX / Swift FX Nano For Her is:

- to be used by patients >30 kg (66lbs) for whom positive airway pressure has been prescribed
- intended for single-patient re-use in the home environment and multipatient 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

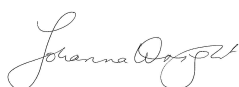
We herewith declare that the above mentioned products are in conformity with the Council Directive 93/42/EEC for medical devices including the MDD amendment 2007/47/EC.

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.

EC140

First issued: 15 March 2013