ResMed

CE 0123

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: Quattro FX NV

Intended Use: The Quattro FX NV is intended to be used with active-exhaust-valve ventilator systems, to provide ventilatory assistance to patients with respiratory insufficiency and respiratory failure.

The Quattro FX NV is:
• to be used by adult patients (> 66 lb/30 kg) requiring non-life-support ventilatory assistance.
• intended for single-patient re-use in the home or multipatient re-use in the hospital/institutional environment.

Classification: IIa according to Rule 2

GMDN: 57814 CPAP/BPAP face 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.

EC127

First issued: 22 September 2011