



Certificate No. 12678-7-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Three Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from August 01, 2019 to July 31, 2021.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturer

ResMed Asia Pte. Ltd.
8 Loyang Crescent
No. 05 - 01
Singapore, SINGAPORE 509016

Legal Manufacturer/Manufacturer

RESMED LTD.
1 ELIZABETH MACARTHUR DRIVE
BELLA VISTA, New South Wales AUSTRALIA 2153

Name of Distributor

Distributor

RESMED CORP
9001 Spectrum Center Boulevard
San Diego, CA USA 92123

---END OF MANUFACTURER/DISTRIBUTOR LIST---





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

Name of Manufacturer

Manufacturer

ResMed Asia Pte. Ltd.
8 Loyang Crescent
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RESMED LTD.
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9001 Spectrum Center Boulevard
San Diego, CA USA 92123

Name of Product(s)

POSITIVE AIRWAY PRESSURE DEVICES

S9 Escape Auto
S9 Elite
S9 AutoSet
S9 Auto25
S9 AutoSet CS
S9 VPAP S
S9 VPAP ST
S9 VPAP ST-A
S9 VPAP TX
AirMini
AirStart 10 APAP
AirSense 10 Elite
AirSense 10 AutoSet
AirSense 10 AutoSet for Her
AirCurve 10 Vauto
AirCurve 10 CS Pacewave
Lumis 100 VPAP S
Lumis 150 VPAP ST
Lumis 150 VPAP ST-A

INVASIVE AND NON-INVASIVE VENTILATOR

Stellar 100
Stellar 150
Astral 100
Astral 150

HUMIDIFIERS

H4i
H5i

CPAP MASKS

NV AcuCare F1-0 Full Face Mask
NV AcuCare F1-1 Full Face Mask
NV AcuCare F1-4 Full Face Mask
AcuCare High Flow Nasal Cannula
AirFit F10 Full Face Mask
AirFit P10 Nasal Pillows Mask
AirMini P10 Setup Pack
AirFit N10 Nasal Mask
AirFit F20 Full Face Mask
AirMini F20 Setup Pack





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3

AirTouch F20 Full Face Mask
AirFit N20 Nasal Mask
AirMini N20 Setup Pack
AirFit N30i
AirFit F30 Full Face Mask
AirFit P30i
Mirage FX Nasal Mask
Mirage Softgel Nasal Mask
Mirage Micro Nasal Mask
Mirage Quattro Full Face Mask
Quattro FX Non-Vented Full Face Mask System
Quattro Air Non-Vented Full Face Mask System
Mirage Non-Vented Full Face Mask System
Ultra Mirage Non-Vented Full Face Mask System
Ultra Mirage Non-Vented Nasal Mask System
Pixi Pediatric Mask
Quattro FX Full Face Mask
Quattro Air Full Face Mask
Swift FX Nano Nasal Mask
Swift LT Nasal Pillows Mask
Hospital Nasal Mask
Hospital Full Face Mask
ACCESSORIES
ApneaLink Air
Adapter
Breathing Circuit
Cables
Cannula
Card Reader
Carry Bag
Circuit
ClimateLine Heated Tube
ClimateLine Max Oxy Heated Tube
ClimateLineAir Heated Tube
ClimateLineAir Oxy Heated Tube
Effort Belt
Mask Elbow
Filter
Filter Heater
FIO2
Gecko Pad
Heated Humidifier Base
HumidAir Cleanable Tub
Humidifier
Humidifier with Water Chamber
HumidX, Humid X Plus
Leakport / Leak Valve
Mask Headgear, Cushion, Frame, Chin Strap, Loops, Clips, Elbows
Mounting
Mouth Piece
Oximetry
Oxygen Monitoring Kit
Passover or Circulating Water Chamber
Power Cable
Power Supply Station / Unit (RPS)
Pressure Transducing System
Remote Alarm
RPS – Power Supply





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Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3

Sensors

SD Card

Temperature Probe

Tubing

Tubing Wrap

TX Link

USB Stick

Water Chamber

Water Trap

Wireless Module

XPOD

EasyCare Online/AirView/MyAir

ResScan, ResTraxx

-----END OF PRODUCT LIST-----

