



Certificate No. 12509-7-2019

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

(One Page)

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 July 26, 2019 to July 25, 2021.





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

Name of Owner Operator

MAXTEC, LLC
2305 South 1070 West
Salt Lake City, UT USA 84119

Name of Manufacturer

MAXTEC, LLC
2305 S 1070 W
Salt Lake City, UT USA 84119

Name of Distributor

MAXTEC, LLC
2305 S 1070 W
Salt Lake City, UT USA 84119

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





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

Name of Manufacturer

MAXTEC, LLC
2305 S 1070 W
Salt Lake City, UT USA 84119

Name of Product(s)

Max Oxygen Replacement Sensors
UltraMax Oxygen Analyzers
MaxO2 A and AE Oxygen Analyzers
Handi+ Oxygen Analyzers
MaxBlend2 Air/Oxygen High and Low Flow Blenders
MaxBlend Lite
MicroMax Air/Oxygen High and Low Flow Blenders
BlenderBuddy and the BlenderBuddy2
MaxVenturi
MaxFlo2 and MaxFlo2 Mini High and Low Flow Air/Oxygen Mixers
Flowmeters and Flowmeter Manifolds
Air/Oxygen Straight and Coiled Hoses
SmartStack IV Stands and Accessories
EyeMax2 Phototherapy Eyemasks

Name of Distributor

MAXTEC, LLC
2305 S 1070 W
Salt Lake City, UT USA 84119

Name of Product(s)

SPO2 Probes and Cables
Spiroquant Flow Sensors
Mysign O Oxygen Analyzers/Monitors
Mysign S Oxygen Analyzers
Pulse Oximeters
MicroBlenders, High and Low Flow

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

