



**Certificate No. 4728-2-2019**

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.

CAPT Sean M. Boyd, MPH, USPHS  
Deputy Director for Regulatory Affairs  
Office of Compliance  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from February 04, 2019 to February 03, 2021.**





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 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**

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Salt Lake City, UT USA 84119

**Name of Manufacturer**

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

**Name of Product(s)**

MAX Oxygen Sensors  
UltraMax Oxygen Analyzers  
MaxO2 A and AE Oxygen Analyzers  
Handi+ Oxygen Analyzers  
MaxO2 ME Oxygen Analyzer/Monitor  
MaxBlend2 Air/Oxygen High and Low Flow Blenders  
MicroMax Air/Oxygen High and Low Flow Blenders  
BlenderBuddy and Blenderbuddy 2  
MaxVenturi  
MaxFlo2 and MaxFlo2 Mini Series High and Low Flow Air/Oxygen Mixers  
Flowmeters and Flowmeter Manifolds  
FloCap and MaxCap Reg CO2 Indicators  
Air/Oxygen Straight and Coiled Hoses  
SmartStack IV Stands and Accessories  
EyeMax2 Phototherapy Eyemasks

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**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 Analyzer/Monitor  
Mysign S Oxygen Analyzer  
Pulse Oximeters  
MicroBlenders High and Low Flow Blenders  
TecoTherm Neo and TecoTherm Supplies  
NAPA LP 15 Pressure Monitor

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

