



**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

Certificate No. 12484-8-2022

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 August 24, 2022 to August 23, 2024.





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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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USA 84119

Name of Manufacturer

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Salt Lake City, UT
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Name of Product(s)

Muffled 2-in-1 Adapter - Tubing, Pressure, and Accessories
Thorpe Tube Flowmeter Manifold
Thorpe Tube Flowmeter
Acrylic Block Flowmeter Manifold
Acrylic Block Flowmeter
MaxO2ME - Oxygen Analyzer/Monitor
EyeMax2 - Phototherapy Eye Mask
MAX Oxygen Sensors
UltraMaxO2 - Oxygen Analyzer
MaxO2+ A/AE - Oxygen Analyzer
Handi+ - Oxygen Analyzer
MaxBlend2 - Air/Oxygen Blender
MaxBlend Lite - Air/Oxygen Blender
MicroMax - Air/Oxygen Blender
BlenderBuddy, BlenderBuddy2 - Air/Oxygen Blender Accessory
MaxVenturi - Air/Oxygen Mixer
MaxFlo2 and MaxFlo2 Mini - Air/Oxygen Mixer
Air/Oxygen Straight and Coiled Hoses
SmartStack IV Stands and Accessories - IV Pole

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
MicroBlender - Air/Oxygen Blender

—END OF PRODUCT LIST—

