



Certificate No. 3757-1-2019

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 January 16, 2019 to January 15, 2021.



E03700407



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

Manufactured for Owner Operator

AIRON CORPORATION
751 North Drive, Unit 6
Melbourne, FL USA 32934

Name of Manufacturer

Manufacturer/Distributor

AIRON CORPORATION
751 North Dr Unit 6
Melbourne, FL USA 32934

----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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Melbourne, FL USA 32934

Name of Manufacturer

Manufacturer/Distributor

AIRON CORPORATION
751 North Dr Unit 6
Melbourne, FL USA 32934

Name of Product(s)

MACS CPAP System
MACS epic CPAP System
pNeuton Model S Ventilator
pNeuton Model A Ventilator
pNeuton Mini Ventilator
Adult / pediatric patient circuit P/N 58001
Adult / pediatric patient circuit P/N 58011
Adult / pediatric patient circuit P/N 58051
Adult / pediatric patient circuit P/N 58301
Neonatal / infant patient circuit P/N 58031
Child / pediatric patient circuit P/N 58035

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



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