



Certificate No. 8115-7-2016

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)

Name of Manufacturer/Distributor, Address

See Attached List

See Attached List

(One Page)

(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.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from August 01, 2016 to July 31, 2018.



E 03197404



Certificate No. 8115-7-2016

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

Name of Owner Operator

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

Name of Manufacturer

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

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



E 03197405



Certificate No. 8115-7-2016

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

Name of Owner Operator

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

Name of Manufacturer

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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

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



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