



**Certificate No. 13237-8-2023**

**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, 2023 to August 23, 2025.**





E04561312



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

**Certificate No. 13237-8-2023**

**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---



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**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**

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

**Name of Product(s)**

pNeuton Model S Ventilator  
pNeuton Model A Ventilator  
MACS CPAP System  
pNeuton Mini Ventilator  
Bacterial filter

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



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