



Certificate No. 6121-3-2024-5

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 (Two Pages)	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 March 14, 2024 to March 13, 2026.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Certificate No. 6121-3-2024-5

Certificate to Foreign Government - Name of Manufacturer/Distributor

Manufactured for Owner Operator

Magnatone Hearing Aid Corp. dba Persona Medical
170 N. Cypress Way
Casselberry, FL
USA 32707

Name of Manufacturer

Magnatone Hearing Aid Corp. dba Persona Medical
170 N. Cypress Way
Casselberry, FL
USA 32707

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



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Certificate No. 6121-3-2024-5

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

Manufactured for Owner Operator

Magnatone Hearing Aid Corp. dba Persona Medical
170 N. Cypress Way
Casselberry, FL
USA 32707

Name of Manufacturer

Magnatone Hearing Aid Corp. dba Persona Medical
170 N. Cypress Way
Casselberry, FL
USA 32707

Name of Product(s)

CS-FP: Claret 300 Full Shell Prewire Power Hearing Aid Sub-Assembly
CS-I: Claret 300 Canal Prewire Hearing Aid Sub-Assembly
CS-IP: Claret 300 Canal Power Prewire Hearing Aid Sub-Assembly
CS-M: Claret 300 Mini Canal Prewire Hearing Aid Sub-Assembly
CS-MP: Claret 300 Mini Canal Power Prewire Hearing Aid Sub-Assembly
CS-C: Claret 300 CIC Prewire Hearing Aid Sub-Assembly
CS-CP: Claret 300 CIC Prewire Power Hearing Aid Sub-Assembly
CS-HP: Claret 300 Half Shell Prewire Power Hearing Aid Sub-Assembly
CS-H: Claret 300 Half Shell Prewire Hearing Aid Sub-Assembly
Claret 365: Behind The Ear 675 Power Hearing Aid (BTE)
Claret 425: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Claret 400: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Claret 450: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
EV-F: Evok 700 Full Shell Prewire Hearing Aid Sub-Assembly
EV-FP: Evok 700 Full Shell Prewire Power Prewire Hearing Aid Sub-Assembly
EV-I: Evok 700 Canal Prewire Hearing Aid Sub-Assembly
EV-IP: Evok 700 Canal Power Prewire Hearing Aid Sub-Assembly
EV-C: Evok 700 CIC Prewire Hearing Aid Sub-Assembly
EV-CP: Evok 700 CIC Power Prewire Hearing Aid Sub-Assembly
ET-F: Evok 500 Full Shell Prewire Hearing Aid Sub-Assembly
ET-FP: Evok 500 Full Shell Prewire Power Prewire Hearing Aid Sub-Assembly
ET-I: Evok 500 Canal Prewire Hearing Aid Sub-Assembly
ET-IP: Evok 500 Canal Power Prewire Hearing Aid Sub-Assembly
ET-C: Evok 500 CIC Prewire Hearing Aid Sub-Assembly
ET-CP: Evok 500 CIC Power Prewire Hearing Aid Sub-Assembly
EN-F: Evok 900 Full Shell Prewire Hearing Aid Sub-Assembly
EN-FP: Evok 900 Full Shell Power Prewire Hearing Aid Sub-Assembly
EN-I: Evok 900 Canal Prewire Hearing Aid Sub-Assembly
EN-IP: Evok 900 Canal Power Prewire Hearing Aid Sub-Assembly
EN-C: Evok 900 CIC Prewire Hearing Aid Sub-Assembly
EN-D: Evok 900 CIC Prewire Hearing Aid Sub-Assembly
EN-CP: Evok 900 CIC Power Prewire Hearing Aid Sub-Assembly
Evok 525: Behind The Ear Hearing Aid (BTE/OTE)
Evok 625: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 927: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 800: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 810: On The Ear Hearing Aid (OTE) Thin Tube
Evok 400: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 1600: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
MF-F: Monet 500 Full Shell Prewire Hearing Aid Sub-Assembly
MF-FP: Monet 500 Full Shell Power Prewire Hearing Aid Sub-Assembly
MF-I: Monet 500 Canal Prewire Hearing Aid Sub-Assembly
MF-IP: Monet 500 Canal Power Prewire Hearing Aid Sub-Assembly
MF-M: Monet 500 Mini Canal Prewire Hearing Aid Sub-Assembly



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Certificate to Foreign Government - Name of Product(s) Attached

MF-C: Monet 500 CIC Prewire Hearing Aid Sub-Assembly
MF-CP: Monet 500 CIC Power Prewire Hearing Aid Sub-Assembly
MF-HP: Monet 500 Half Shell Power Prewire Hearing Aid Sub-Assembly
MF-H: Monet 500 Half Shell Prewire Hearing Aid Sub-Assembly
MT-F: Monet 300 Full Shell Prewire Hearing Aid Sub-Assembly
MT-FP: Monet 300 Full Shell Power Prewire Hearing Aid Sub-Assembly
MT-M: Monet 300 Mini Canal Prewire Hearing Aid Sub-Assembly
MT-MP: Monet 300 Mini Canal Power Hearing Aid Sub-Assembly
MT-I: Monet 300 Canal Prewire Hearing Aid Sub-Assembly
MT-IP: Monet 300 Canal Power Prewire Hearing Aid Sub-Assembly
MT-C: Monet 300 CIC Hearing Aid Sub-Assembly
MT-CP: Monet 300 CIC Power Prewire Hearing Aid Sub-Assembly
MT-HP: Monet 300 CIC Half Shell Prewire Power Hearing Aid Sub-Assembly
MT-H: Monet 300 CIC Half Shell Prewire Hearing Aid Sub-Assembly
OE-F: Olé 2100 Full Shell Prewire Prewire Hearing Aid Sub-Assembly
OE-FP: Olé 2100 Full Shell Power Prewire Hearing Aid Sub-Assembly
OE-I: Olé 2100 Canal Prewire Hearing Aid Sub-Assembly
OE-IP: Olé 2100 Canal Power Prewire Hearing Aid Sub-Assembly
OE-C: Olé 2100 CIC Prewire Hearing Aid Sub-Assembly
OE-CP: Olé 2100 CIC Power Prewire Hearing Aid Sub-Assembly
OE-HP: Olé 2100 Half Shell Power Prewire Hearing Aid Sub-Assembly
OE-H: Olé 2100 Half Shell Prewire Hearing Aid Sub-Assembly
OE-D: Olé 2100 IIC Prewire Hearing Aid Sub-Assembly
OLE2: In The Ear Open Fit
OLE-HD: Olé Hidden Deep Prewire
OLE ICO: In The Canal Open
OLE 2123/25 OTE Mini BTE 312
OL-C Ole CIC Prewire Hearing Aid Sub-Assembly
OL-CP Ole CIC Power Prewire Hearing Aid Sub-Assembly
OL-I Ole ITC Prewire Hearing Aid Sub-Assembly
OL-IP Ole ITC Power Prewire Hearing Aid Sub-Assembly
OL-M Ole Mini Prewire Hearing Aid Sub-Assembly
OL-MP: Ole Mini Power Prewire Hearing Aid Sub-Assembly
Ole 2125: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Ole 2127: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Ole 2127r: Behind The Ear/On the Ear Hearing Aid (RIC)
Sombra VS: Wireless Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Sombra VR: Wireless Behind The Ear/On the Ear Hearing Aid (RIC)
Sombra XS: Wireless Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Sombra XR: Wireless Behind The Ear/On the Ear Hearing Aid (RIC)
Sombra 9S: Wireless Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Sombra 9R: Wireless Behind The Ear/On the Ear Hearing Aid (RIC)
Sombra 9P: Wireless Behind The Ear/On the Ear Hearing Aid (BTE)
RXEars RX-8: Wireless Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
RXEars RX-4: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
RXEars RX-I: In The Canal Hearing Aid (ITC)
RXEars RX-S: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)

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