



**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. 9299-4-2018

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

(Three Pages)

Name of Manufacturer/Distributor, Address

Manufactured for Owner Operator

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

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 April 17, 2018 to April 16, 2020.





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Manufactured for Owner Operator

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

Name of Product(s)

CO-F: Claret 100 Full Shell Prewire Hearing Aid Sub-Assembly
CO-FP: Claret 100 Full Shell Prewire Power Hearing Aid Sub-Assembly
CO-H: Claret 100 Half Shell Prewire Hearing Aid Sub-Assembly
CO-HP: Claret 100 Half Shell Prewire Power Hearing Aid Sub-Assembly
CO-I: Claret 100 Canal Prewire Hearing Aid Sub-Assembly
CO-IP: Claret 100 Canal Prewire Power Hearing Aid Sub-Assembly
CO-M: Claret 100 Mini Canal Prewire Hearing Aid Sub-Assembly
CO-MP: Claret 100 Mini Canal Prewire Power Hearing Aid Sub-Assembly
CO-C: Claret 100 CIC Prewire Hearing Aid Sub-Assembly
CO-CP: Claret 100 CIC Prewire Power Hearing Aid Sub-Assembly
CS-F: Claret 300 Full Shell Prewire Hearing Aid Sub-Assembly
CS-FP: Claret 300 Full Shell Prewire Power Hearing Aid Sub-Assembly
CS-H: Claret 300 Half Shell Prewire Hearing Aid Sub-Assembly
CS-HP: Claret 300 Half Shell Power Prewire 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 Prewire Hearing Aid Sub-Assembly
CS-CP: Claret 300 CIC Prewire Power Hearing Aid Sub-Assembly
Claret 320: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Claret 325: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Claret 330: Behind The Ear Hearing Aid (BTE)
Claret 334: Behind The Ear Hearing Aid (BTE)
Claret 360: Behind The Ear 675 Power Hearing Aid (BTE)
Claret 365: Behind The Ear 675 Power Hearing Aid (BTE)
Claret 335: Behind The Ear 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 Prewire Hearing Aid Sub-Assembly
EV-FP: Evok 700 Full Shell Prewire Power Prewire Hearing Aid Sub-Assembly
EV-H: Evok 700 Half Shell Prewire Hearing Aid Sub-Assembly
EV-HP: Evok 700 Half Shell Power Prewire Hearing Aid Sub-Assembly
EV-I: Evok 700 Canal Prewire Prewire Hearing Aid Sub-Assembly
EV-IP: Evok 700 Canal Power Prewire Hearing Aid Sub-Assembly
EV-M: Evok 700 Mini Canal Prewire Hearing Aid Sub-Assembly
EV-MP: Evok 700 Mini Canal Power Prewire Hering 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 Prewire Hearing Aid Sub-Assembly
ET-FP: Evok 500 Full Shell Power Prewire Prewire Hearing Aid Sub-Assembly
ET-H: Evok 500 Half Shell Prewire Hearing Aid Sub-Assembly
ET-HP: Evok 500 Half Shell Power Prewire Hearing Aid Sub-Assembly
ET-I: Evok 500 Canal Prewire Prewire Hearing Aid Sub-Assembly
ET-IP: Evok 500 Canal Power Prewire Hearing Aid Sub-Assembly
ET-M: Evok 500 Mini Canal Prewire Hearing Aid Sub-Assembly
ET-MP: Evok 500 Mini 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





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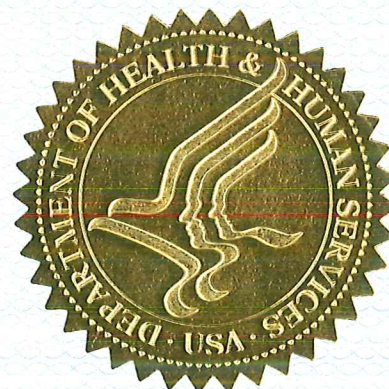
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EN-H: Evok 900 Half Shell Prewire Hearing Aid Sub-Assembly
EN-HP: Evok 900 Half Shell Power Prewire Hearing Aid Sub-Assembly
EN-I: Evok 900 Canal Prewire Hearing Aid Sub-Assembly
EN-IP: Evok 900 Canal Power Prewire Hearing Aid Sub-Assembly
EN-M: Evok 900 Mini Canal Prewire Hearing Aid Sub-Assembly
EN-MP: Evok 900 Mini Canal Power Prewire Hearing Aid Sub-Assembly
EN-C: 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 520r: Behind The Ear/On the Ear Hearing Aid (RIC)
Evok 625: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 937: Behind The Ear Hearing Aid (BTE)
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)
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-H: Monet 500 Half Shell Prewire Hearing Aid Sub-Assembly
MF-HP: Monet 500 Half Shell Power Prewire Hearing Aid Sub-Assembly
MF-M: Monet 500 Mini Canal Prewire Hearing Aid Sub-Assembly
MF-MP: Monet 500 Power Mini Canal Prewire Hearing Aid Sub-Assembly
MF-C: Monet 500 CIC Prewire Hearing Aid Sub-Assembly
MF-CP: Monet 500 CIC Power 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-H: Monet 300 CIC Half Shell Prewire Hearing Aid Sub-Assembly
MT-HP: Monet 300 CIC Half 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 Prewire 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
Monet 320: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Monet 325: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Monet 330: Behind The Ear Hearing Aid (BTE/OTE)
Monet 530: Behind The Ear Hearing Aid (BTE/OTE)
Monet 537: Behind The Ear Hearing Aid (BTE)
OE-F: Olé 2100 Full Shell 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-M: Olé Mini Canal Prewire Hearing Aid Sub-Assembly
OE-MP: Olé Mini 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-F: Olé Full Shell Prewire Hearing Aid Sub-Assembly
OL-FP: Olé Full Shell Power Prewire Hearing Aid Sub-Assembly





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OL-H: Olé Half Shell Prewire Hearing Aid Sub-Assembly
OL-HP: Olé Half Shell Power Prewire Hearing Aid Sub-Assembly
OL-C Olé CIC Prewire Hearing Aid Sub-Assembly
OL-CP Olé CIC Power Prewire Hearing Aid Sub-Assembly
OL-I Olé ITC Prewire Hearing Aid Sub-Assembly
OL-IP Olé ITC Power Prewire Hearing Aid Sub-Assembly
OL-M Olé Mini Prewire Hearing Aid Sub-Assembly
OL-MP: Olé 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)
Opa 200: Behind The Ear/On the Ear Hearing Aid (RIC)
Opa 300: Behind The Ear/On the Ear Hearing Aid (RIC)

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

