



**Certificate No. 12516-8-2020**

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**

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 10, 2020 to August 09, 2022.**





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

**Name of Corporate Headquarters**

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 Distributor**

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

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







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**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3**

**Name of Corporate Headquarters**

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 Distributor**

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-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-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 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-I Evok 700 Canal Prewire 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 Prewire Hearing Aid Sub-Assembly  
ET-FP Evok 500 Full Shell Prewire 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-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 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







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- 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 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)
- 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 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
- 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
- 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 Ole 2100 Full Shell Prewire Prewire Hearing Aid Sub-Assembly
- OE-FP Ole 2100 Full Shell Power Prewire Hearing Aid Sub-Assembly
- OE-I Ole 2100 Canal Prewire Hearing Aid Sub-Assembly
- OE-IP Ole 2100 Canal Power Prewire Hearing Aid Sub-Assembly
- OE-C Ole 2100 CIC Prewire Hearing Aid Sub-Assembly
- OE-CP Ole 2100 CIC Power Prewire Hearing Aid Sub-Assembly
- OE-HP Ole 2100 Half Shell Power Prewire Hearing Aid Sub-Assembly
- OE-H Ole 2100 Half Shell Prewire Hearing Aid Sub-Assembly
- OE-D Ole 2100 IIC Prewire Hearing Aid Sub-Assembly
- OLE2 In The Ear Open Fit
- OLE-HD Ole Hidden Deep Prewire
- OLE IC Ole In The Canal Open
- OLE 2T 2325 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 IIC Prewire Hearing Aid Sub-Assembly
- OL-IP Ole IIC 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 21 25 Behind The Ear/On the Ear Hearing Aid (BTE/OTE)





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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)  
Sombra 8s Behind The Ear/On the Ear Hearing Aid (BTE/OTE)  
Sombra 8p Behind The Ear Hearing Aid (BTE)  
Sombra 8r Behind The Ear/On the Ear Hearing Aid (RIC)  
Sombra 4s Behind The Ear/On the Ear Hearing Aid (BTE/OTE)  
Sombra 4p Behind The Ear Hearing Aid (BTE)  
Sombra 4r Behind The Ear/On the Ear Hearing Aid (RIC)  
SG-F Sombra 8CH Full Shell Prewire Hearing Aid Sub-Assembly  
SG-FP Sombra 8CH Full Shell Power Prewire Hearing Aid Sub-Assembly  
SG-HP Sombra 8CH Half Shell Power Prewire Hearing Aid Sub-Assembly  
SG-H Sombra 8CH Half Shell Prewire Hearing Aid Sub-Assembly  
SG-I Sombra 8CH Canal Prewire Hearing Aid Sub-Assembly  
SG-IP Sombra 8CH Canal Power Prewire Hearing Aid Sub-Assembly  
SG-M Sombra 8CH Mini Canal Prewire Hearing Aid Sub-Assembly  
SG-MP Sombra 8CH Mini Canal Power Prewire Hearing Aid Sub-Assembly  
SG-C Sombra 8CH CIC Prewire Hearing Aid Sub-Assembly  
SG-CP Sombra 8CH CIC Power Prewire Hearing Aid Sub-Assembly  
SF-F Sombra 4CH Full Shell Prewire Hearing Aid Sub-Assembly  
SF-FP Sombra 4CH Full Shell Power Prewire Hearing Aid Sub-Assembly  
SF-HP Sombra 4CH Half Shell Prewire Hearing Aid Sub-Assembly  
SF-H Sombra 4CH Half Shell Power Prewire Hearing Aid Sub-Assembly  
SF-I Sombra 4CH Canal Prewire Hearing Aid Sub-Assembly  
SF-IP Sombra 4CH Canal Power Prewire Hearing Aid Sub-Assembly  
SF-M Sombra 4CH Mini Canal Prewire Hearing Aid Sub-Assembly  
SF-MP Sombra 4CH Power Mini Canal Prewire Hearing Aid Sub-Assembly  
SF-C Sombra 4CH CIC Prewire Hearing Aid Sub-Assembly  
SF-CP Sombra 4CH CIC Power Prewire Hearing Aid Sub-Assembly

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

