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. 9074-6-2026-1

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

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor
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.

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 June 09, 2026 to June 08, 2028.

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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer/Distributor

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

Name of Product(s)

DEVICE,ANTI-STAMMERING
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 Prewire Power Hearing Aid Sub-Assembly
CS-I: Claret 300 Canal Shell Prewire Hearing Aid Sub-Assembly
CS-IP: Claret 300 Canal Shell Prewire Power Hearing Aid Sub-Assembly
CS-M: Claret 300 Mini Canal Prewire Hearing Aid Sub-Assembly
CS-MP: Claret 300 Mini Canal Prewire Power 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
Claret 365: Behind The Ear 675 Power Hearing Aid (BTE)
Claret 400: Behind The Ear /On the Ear Hearing Aid (BTE/OTE)
Claret 425: Behind The Ear /On the Ear Hearing Aid (BTE/OTE)
Claret 450: Behind The Ear /On the Ear Hearing Aid (BTE/OTE)
EF-F: Evok 540 Full Shell Prewire Hearing Aid Sub-Assembly
EF-FP: Evok 540 Full Shell Prewire Power Hearing Aid Sub-Assembly
EF-H: Evok 540 Half Shell Prewire Hearing Aid Sub-Assembly
EF-HP: Evok 540 Half Shell Prewire Power Hearing Aid Sub-Assembly
EF-I: Evok 540 Canal Prewire Hearing Aid Sub-Assembly
EF-IP: Evok 540 Canal Prewire Power Hearing Aid Sub-Assembly
EF-M: Evok 540 Mini Canal Prewire Hearing Aid Sub-Assembly
EF-MP: Evok 540 Mini Canal Prewire Power Hearing Aid Sub-Assembly
EF-C: Evok 540 CIC Prewire Hearing Aid Sub-Assembly
EF-CP: Evok 540 CIC Prewire Power Hearing Aid Sub-Assembly
SX-F: Evok 1600 Full Shell Prewire Hearing Aid Sub-Assembly
SX-FP: Evok 1600 Full Shell Prewire Power Hearing Aid Sub-Assembly
SX-H: Evok 1600 Half Shell Prewire Hearing Aid Sub-Assembly
SX-HP: Evok 1600 Half Shell Prewire Power Hearing Aid Sub-Assembly
SX-I: Evok 1600 Canal Prewire Hearing Aid Sub-Assembly
SX-IP: Evok 1600 Prewire Power Hearing Aid Sub-Assembly
SX-M: Evok 1600 Mini Canal Prewire Hearing Aid Sub-Assembly
SX-MP: Evok 1600 Prewire Power Hearing Aid Sub-Assembly
SX-C: Evok 1600 CIC Prewire Hearing Aid Sub-Assembly
SX-CP: Evok 1600 Prewire Power Hearing Aid Sub-Assembly
EVOK 525: 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 400: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
Evok 1600: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
OLE 2123: Behind The Ear/On the Ear Hearing Aid (BTE/OTE)
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: Behind The Ear/On the Ear Hearing Aid (OTE/BTE)

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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)
Evok Ri: Wireless Behind The Ear/On the Ear Hearing Aid (RIC)
----------END OF PRODUCT LIST----------