



Food and Drug Administration Notice

The Food and Drug Administration has determined that a person with impaired hearing should have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid; licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to insure that all conditions that may affect hearing are identified and, if possible, medically treated before a hearing aid is purchased.

At your own expense, your physician may conduct an exam to insure there are no underlying medical conditions that need to be addressed. As a part of the exam, the physician might have an audiologist or other hearing health professional conduct a hearing test. If appropriate the physician will provide a completed Medical Clearance form stating that you are medically cleared to wear hearing aids. Under federal law the healthcare provider must also provide you with a copy of the hearing test results upon your request.

If you do not want a medical examination, federal law allows for a fully informed adult to sign a "Medical Exam Waiver Statement" declining the medical evaluation.

However, EAR Audiology, Inc. requires most prospective hearing aid buyers to consult with a licensed physician (preferably an ear specialist) whenever any of the following conditions are present:

- Visible congenital or traumatic deformity of the ear
- History of active drainage from the ear within the previous 90 days
- History of sudden or rapidly progressive hearing loss within the previous 90 days
- Acute or chronic dizziness

- Unilateral (one ear only) hearing loss of sudden or recent onset within the previous 90 days
- Audiometric air-bone gap equal to or greater than 15 decibels at 500 Hertz (Hz), 1000 Hz, and 2000 Hz
- Visible evidence of significant cerumen (wax) accumulation or a foreign body in the ear canal
- Pain or discomfort in the ear
- Acute or chronic numbness or tingling in the face
- Unilateral or pulsatile tinnitus (ringing in the ear)

If any of the above conditions are present, a Medical Exam Waiver is allowed only if the condition is longstanding, stable and clearly documented with a previous Medical Clearance.



Medical Exam Waiver Statement

I have been advised by EAR Audiology, Inc., including any or all of its representatives, that the Food and Drug Administration (FDA) has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid.

I do not want a medical evaluation before purchasing a hearing aid.

Waiver Signature

Date

By signing the above line, you are also stating that you are age 18 years of age or older, you have read and understand the required FDA Notice, and you have made an informed decision to purchase hearing aids without being seen by a physician. Additionally, by purchasing hearing aids from EAR Audiology, Inc. you agree that you are the person that will be the end user and wearer of the hearing aids. You also agree that the reason for purchasing hearing aids from EAR Audiology, Inc. is for the purpose of personal use only and not for competitive research, resale or any other reason.