

# IN-THE-EAR HEARING AIDS

## User Manual

- sino
- kami
- rega




# CONTENTS

## Intended purpose

Hearing aids reduce the effects of hearing loss as much as possible. Personal discomfort thresholds in loud noises are also taken into account.

In quiet environments as well as in situations with background noise, speech intelligibility should be improved and hearing effort reduced.

 The hearing aids are designed to last 6 years. Further restrictions on use are listed in section 9 Safety instructions.

 Hearing aids and the noiser module must be individually fitted by a hearing care professional or an ENT doctor.

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## 1 INTRODUCTION

Congratulations on the purchase of your new audifon hearing aids. Your hearing care professional has adjusted the hearing aids to your individual requirements. These instructions are therefore intended to help you use your audifon hearing aids properly.

Please read through the following operating and care instructions carefully to avoid malfunctions and faults. If you follow these instructions, your hearing aids will prove an invaluable help in day-to-day communication with your surroundings and other people.

The specific model of your hearing aids is shown on the sticker on the packaging, on the warranty card or printed on the hearing aids themselves.

Please take note of the following:

Your hearing aid will not make your hearing normal again, nor will it prevent or improve any physical hearing loss. If you fail to wear your hearing aid regularly, you will not benefit fully from it. Use of a hearing aid only accounts for part of your hearing ability and may need to be supplemented by auditory training and instruction in lip reading.

If you have any further questions, please contact your hearing care professional.

## 2 YOUR HEARING AID

### 2.1 Type

Your hearing aids are in-the-ear hearing aids.

### 2.2 Technical features

This user manual applies to the following types:

Model	Battery		Gain in dB	Indication range
	Size	Average service life (zinc air) in h		
rega pico	10	60	41	Minor to moderate hearing loss
rega CIC	10	60	50	
kami CIC	10	60	50	
sino CIC	10	60	50	
rega ITE V50	312/13	110/180	50	Minor to moderate hearing loss
kami ITE V50	312/13	110/180	50	
sino ITE V50	312/13	110/180	50	
rega ITE V60	312/13	110/170	61	Minor to severe hearing loss
kami ITE V60	312/13	110/170	61	
sino ITE V60	312/13	110/170	61	
rega ITE V70	312/13	90/160	70	Moderate to severe hearing loss
kami ITE V70	312/13	90/160	70	
sino ITE V70	312/13	90/160	70	

The detailed acoustic data of your hearing aid can be found in a separate data specification. This and further information are available from your hearing care professional or [www.audifon.com](http://www.audifon.com).

### 2.3 Batteries

To start your hearing aids, first insert a battery in the battery compartment.

Make sure you only use zinc air batteries. Please follow the instructions on the battery packaging. For the exact type of battery in your hearing aid please see the overview table.


Please dispose of used batteries in the appropriate containers at the premises of your hearing care professional.

Always switch your hearing aids OFF after use. To avoid damage, remove the battery if you do not intend to use the hearing aids for a long time.

#### 2.3.1 Information on battery

A zinc air battery is used to supply the power for your hearing aids. This type of battery is only activated when oxygen comes through the air holes into the button cell and a chemical reaction is initiated. During production, the air holes are sealed with a protective strip.

This ensures the battery remains fresh until use and lasts longer when it is sealed. Removing the protective strip allows oxygen to enter and the chemical reaction is initiated.

 Refitting the strip when the battery is not in use will not extend its service life.

☞ Battery should be stored at room temperature. Avoid keeping them in hot places or rooms with high humidity (e.g. bathroom). Storage in a cooled location is not necessary.

☞ Used batteries are considered hazardous materials and contain toxic materials, should never be disposed of in the trash. Ask about recycling programs in your area where you live or return them to your hearing care professional to dispose them appropriately.

☞ Further safety instructions can be found on the battery packaging.

### 2.3.2 Low battery warning

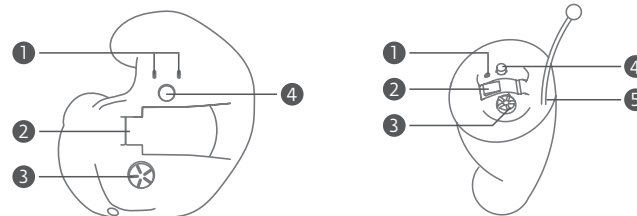
The hearing aids are equipped with a low battery signal which can be heard as a series of beeps approximately 30 minutes before the end of the battery life.

## 3 OPERATION – SINO, KAMI, REGA

### 3.1 Construction

Your hearing aid consists of the following elements:

- 1 Microphone inlets
- 2 Battery compartment
- 3 Volume control\*
- 4 Program switch\*
- 5 Drawstring\*



☞ Your hearing aids may differ from the illustrations as they have been made according to an individual impression taken of your ear.

☞ Depending on which type of hearing aid you have, it may not feature the elements marked with an \*.

☞ Depending on the model, your hearing aids have markings for the sides: blue = left, red = right

### 3.2 Inserting battery



Remove a battery from its packaging.

If the battery has a protective film, remove and wait a few minutes before inserting the battery.



Open the battery compartment carefully with your fingernail at the edge for opening and swing it right out.



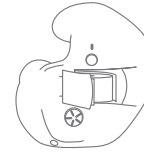
Then insert the battery in the battery compartment. Make sure the (+) symbol on the battery matches the (+) symbol on the battery compartment.

ⓘ **Note:** Do not force the battery into the battery compartment. If it does not fit, check whether you are inserting it correctly and that it is the correct type of battery (see Section 2.2).

### 3.3 Removing battery



Open the battery compartment carefully with your fingernail at the edge for opening and swing it right out.



Then remove the battery from the battery compartment.

### 3.4 Switching hearing aids on and off



on

#### Switching on

Your hearing aids are switched on and off via the battery compartment.

The hearing aids are now switched on as soon as the battery compartment is closed.

After a preset delay and a start-up jingle, the first program will activate and the hearing aids are ready for use.



off


#### Switching off

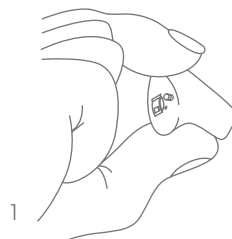
The hearing aids are switched off as soon as the battery compartment is opened.

If the devices are going to be out of use for a long time, open the battery compartment fully and remove the battery.

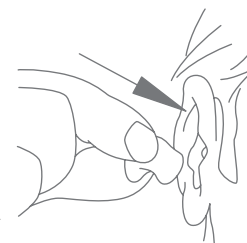
### 3.5 Inserting and removing hearing aids

Before use, check that your hearing aids are clean. After use, earwax and other residues may be present on your hearing aids. Remove before using again.

 Depending on the model, your hearing aids have markings for the sides: blue = left, red = right



1



2



3



4

#### Inserting

Insert your hearing aids in the outer part of the ear so that the tip points towards the ear canal. To insert, pull your earlobe down slightly and at the same time press the hearing aid into your ear. Your hearing aid will then slide into the right position.

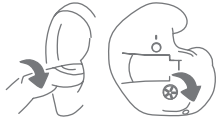
#### Removing

Take your hearing aid out by pulling your earlobe with one hand and pushing gently behind the ear. This will release the hearing aid from the ear canal.

If your hearing aid has a drawstring, use it to carefully pull the hearing aid out of your ear.

### 3.6 Volume control and program selection

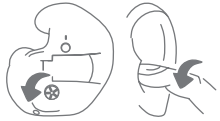
#### 3.6.1 Volume selection



right ear

When you switch your hearing aids on, they will be at the volume set for you.

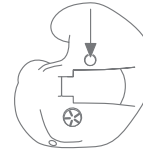
- **Increase volume**  
Slowly turn the controller forwards.
- **Reduce volume**  
Slowly turn the controller backwards.



left ear

Once you have reached the upper or lower volume limit, you will hear a clear signal.

#### 3.6.2 Selecting hearing programs (for hearing aids with a program switch)



Press the program switch on your devices to run through the various hearing programs.

Each time you press the program switch, the next hearing program will be activated. An audible signal confirms each program change.

Hearing program	Description of setting
1	_____
2	_____
3	_____
4	_____



## 4 TINNITUS FUNCTION

Combi hearing aids from audifon play an effective part in tinnitus therapy.


Your hearing care professional would have adjusted the combi hearing aids to your individual hearing situation with you.

Information on operating devices with active tinnitus modules can be found in Section 3 on this user manual.


### 4.1 Intended purpose

The integrated noiser module can be optionally activated and can be used to support tinnitus therapy.

In combination with other therapeutic measures, the noise is intended to help reduce the perception of tinnitus.

 Activation of the noiser module as part of a tinnitus therapy is suitable for adults aged 18 and over.

## 5 MAKING PHONE CALLS

 Depending on which type of hearing aid you have, it may not feature the elements marked with an \*.

### 5.1 Telephone loop (T-Coil)\*

A telephone loop receives the magnetic signal from telephones and converts it to sound. This optional telephone program may help you to understand better what people are saying on the telephone.

When making calls with the telephone loop program, hold the handset as normal.

 To find the correct position for optimum reception, move the handset backwards and forwards slightly.

### 5.2 Automatic program change\*

The hearing aids belonging to the kami and rega families feature automatic telephone program activation. The hearing aids can automatically switch either to telephone loop (Auto T-Coil) or to a microphone program for telephony (Auto Phone).

To prevent the hearing aids from accidentally switching programmes during a telephone call, the program switch is disabled during this time.

### 5.2.1 Auto T-Coil

Automatic switchover to the telephone loop program is designed for landline phones and only works with older telephones or phones which have been specially designed for use with telephone loops. Attaching the optional magnet sticker increases the reliability of the switching function. Familiarise yourself with how the automatic telephone loop switching function works before making a call.


When you move the telephone handset away from your ear again, your hearing aids will return to the program previously in use.

### 5.2.2 Auto Phone

Automatic switchover to an acoustic telephone program can be used with conventional landline and mobile phones and optimises playback for telephony.

Attaching the optional magnet sticker increases the reliability of the switching function. Familiarise yourself with how the automatic telephone program switching function works before making a call.

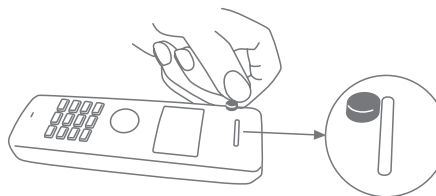
When you move the telephone handset away from your ear again, your hearing aids will return to the program previously in use.

 Auto Phone and Auto T-Coil are optional functions. Your hearing care professional will adjust your devices to your individual requirements.

### 5.2.3 Attaching magnet

To attach the magnet, proceed as follows:

1. Clean the telephone handset thoroughly.
2. Attach the magnet as shown in the illustration.
3. If necessary, you can reposition the magnet.



## 6 ACCESSORIES

The hearing aids from the rega, kami and sino families offer the following accessories, which are available from your hearing care professional. For further information please contact your hearing care professional.

Accessories	Description
Earwax filter	Small filter that stops the sound outlet of your hearing aid getting blocked and should be replaced regularly.

## 7 CARE INSTRUCTIONS

### 7.1 General

audifon hearing aids will improve your hearing ability as well as your quality of life. To ensure your hearing aids function perfectly and so make hearing a pleasant experience for years to come, audifon offers special care products designed to enable optimum cleaning of your devices.

Protect your hearing aids against moisture (e.g. showers, sweat, rain), and take your hearing aids out before using hairspray or similar cosmetic products.

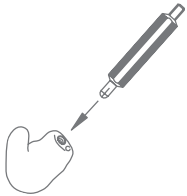
No matter what type of hearing aid you use, we also recommend carrying out daily care on them as these devices are exposed to moisture and dust through intended use, even when handled with care: Each one is in direct contact with the skin. Resulting perspiration may damage your hearing aid in the long term unless dried on a daily basis. The hearing aids are coated with a water-repellent finish to prevent any damage from moisture.

Wearing a hearing aid or insertion of the ear adapter piece in the ear canal will always involve soiling with earwax. For this reason we recommend regular cleaning. Do not use a damp cloth to clean your hearing aids. Always use a soft, dry cloth.

Should your hearing aid still not function correctly despite regular care, call on your hearing care professional. Do not try under any circumstances to repair your hearing aid yourself.

## 7.2 Changing earwax protection filter

Your hearing aids have protection filters to prevent earwax being deposited inside the receiver. It is necessary to regularly change the filter to ensure your hearing aids function perfectly. To replace the filter, proceed as follows:



Remove the replacement tool from the filter dispenser and slide it into the filter.

Remove the filter.

Turn the replacement tool so the new filter is at the bottom.

Press the new filter with the replacement tool into the filter opening of the hearing aid until it clicks into place. Then simply pull out the replacement tool and dispose of it.

## 7.3 Drying hearing aids

Your hearing aids should be dried after use at the end of the day and above all after cleaning. If you take care of your hearing aids by drying them carefully, this will significantly increase their service life. There are two ways of doing this. If you have an audifon drying station of the type dry star UV 2 or dry go, use this for drying. Take note of the individual product instructions for further details. Alternatively, you can dry your hearing aids in the audifon pro care Drying-Tub with an audifon Drying-Capsule.

### **dry star UV 2**

The audifon dry star UV 2 will dry your devices gently yet thoroughly through a constant circulation of uniformly warm air inside the casing.

The audifon dry star UV 2 is not only automatic but also consumes very little power, switching itself off at the end of the drying program. The drying station is simple to operate using a single sensor button.



## dry go

The audifon dry go is the perfect solution for drying your devices when on trips or if out and about. Once connected, for example to the USB port on your laptop, the drying program can be conveniently started at the touch of a single button. A flow of warm air inside the audifon dry go will then dry your devices reliably. The drying station switches off automatically at the end of the drying program.



## 8 TROUBLESHOOTING

If you experience any malfunctions when using your hearing aids, this does not necessarily mean that they are faulty. Therefore first check your hearing aid to make sure that:

- the hearing aid is switched on (see "Switching on and off" Section 3.4),
- the batteries are not weak or dead,
- the volume control is not at the lowest setting (increase the volume slightly if necessary),
- the right program has been set (change program if necessary),
- the earwax protection system is not blocked.

If this does not eliminate the fault, consult your hearing care professional, who will be pleased to help you.

### ⓘ **Note: Malfunctions!**

Your devices may be subject to interference from other electrical equipment despite their EMC-compatible design. If this occurs, please consult your hearing care professional.

## 9 SAFETY INFORMATION

### 9.1 Important warnings

#### **Warning: Risk of suffocation!**

Batteries, hearing aids and other small parts (e.g. magnets) may be swallowed. For this reason, these hearing aids are not intended for use by children under 36 months of age. Never leave children unattended with your hearing aids! Should a battery, hearing aid or other small parts be accidentally swallowed, please consult a doctor immediately.

#### **Warning: Damage to hearing!**

The maximum volume of the noiser modul is in a range that may lead to hearing loss according to OSHA regulations. For users without hearing loss, the noiser modul should not exceed sound pressure levels above 70 dB SPL (as measured at a 2cc coupler). For users with hearing loss, the hearing loss needs to be taken into consideration when adjusting the noise levels. Under no circumstances should the noiser module be used at a volume that is uncomfortable to the user.

For sound pressure levels up to 80 db SPL (as measured at the 2cc coupler) the noiser module can be used for up to 8 hours daily. For higher sound pressure levels, the uncritical duration of applications is reduced. The noiser modul should not be used for more than 2 hours daily at higher sound pressure levels. Higher sound levels and/or longer times of application might harm the hearing ability over time.

#### **Warning: Risk of explosion!**

Do not use hearing aids in environments where there is a risk of explosion (e.g. in mines or industrial plants subject to such risk).

#### **Warning: Skin irritation**

If you are allergic to acrylic, symptoms of an allergy may occur. In this case please consult your doctor.

#### **Warning: Risk of injury!**

Hearing aids are adjusted to the individual hearing loss of each wearer and should therefore only be used by this person.

If the hearing aid is worn by other persons, this may harm their hearing.

#### **Warning: Interference with active and inactive implants!**

If you have an active or inactive implant (e.g. defibrillator, pacemaker), follow the implant manufacturer's instructions regarding the use of mobile devices. In the event of malfunctions, stop using your hearing aid and contact your doctor or the implant manufacturer.

If you have an active brain implant, ask your doctor or the implant manufacturer for a risk assessment.

#### **Warning: Risk of injury!**

During the fitting process, please only use accessories (e.g. measurement technology, in-situ hoses, sound hoses, filters) that are approved in the EU for the respective purpose and, thus, that are compliant with the "General Requirements" of Directive 93/42 / EU or the Regulation 2017/745 / EU for medical devices, respectively. Please pay attention to the corresponding CE marking. For example: Affinity 2.0 from Interacoustics and the Sanibel™ REM probe tubes, type A from Sanibel Supplies. Unauthorized changes or modifications that are not explicitly approved can – in the worst case – lead to injuries.

**⚠ Warning: Electric shock!**

Audio devices supplied with mains power must comply with IEC 60065, IEC 60601 or similar safety standards to ensure that they can be connected to your hearing aids without any risk to safety.

## 9.2 Information about product safety

**⚠ Note: Damage to hearing aid!**

Hearing aids are susceptible to impact, so avoid any hard knocks (e.g. by dropping them).

**⚠ Note: Modifications to the device!**

No modifications should be made to the hearing aids unless performed directly by the manufacturer.

**⚠ Note: Damage to hearing aid!**

To avoid damage to your hearing aids, please do not wear them in the following situations:

- when swimming, in the shower or bath
- when washing or blow-drying your hair
- when using hair spray, perfume, aftershave or body lotion
- during high-frequency heat therapy treatment
- when it is very hot or raining heavily

Should your hearing aid become damp, remove the battery and dry the hearing aid in one of the drying containers specified by the manufacturer. Do not dry your hearing aid in the microwave under any circumstances.

**⚠ Note: Damage to hearing aid!**

Do not force the battery into the battery compartment. If it does not fit, check whether you are inserting it correctly and that it is the correct type of battery.

**⚠ Note: Interference with electronic devices!**

If you are in an environment where use of electronic or wireless devices is restricted, check whether your hearing aids must be turned off.

**⚠ Note: Leaking batteries can damage your hearing aid!**

If you are not going to use your hearing aids for a long time, remove the battery to increase its service life, to avoid leakage and to prevent corrosion to the battery contacts.

**⚠ Note: Interference with magnetic storage media!**

Magnets pose a risk when they are placed close to magnetic storage media. Please therefore keep magnets away from such media (e.g. bank cards).

**⚠ Note: Strong radiation can damage hearing aids!**

Make sure you take out your hearing aids if you are undergoing a CT or MRI scan, other magnetic field-based examinations or radiotherapy.

**⚠ Note: Damage to hearing aid!**

Never leave your hearing aid in the sun, near a naked flame or in a hot vehicle. Otherwise your hearing aids might become damaged.

**⚠ Note: Damage to hearing aid!**

Never try to change the shape of your hearing aid yourself. Otherwise your hearing aids might become damaged.

**⚠ Note: Malfunctions!**

Your devices may be subject to interference from other electrical equipment despite their EMC-compatible design. In this case move away from the source of interference.

❗ **Note: Leaking batteries can damage your hearing aid hearing aid!**

If you do not intend to use your hearing aids for a long time, remove the battery to increase its service lifespan, to avoid leakage and to prevent corrosion to the battery contacts.

❗ **Note: Age of user!**

The hearing aids are not suitable for children and teenagers under the age of 16 years.

❗ **Note: Reporting serious incidents!**

All serious incidents that occur involving the product should be reported to the manufacturer and the competent authorities in the member state in which the user and/or the patient are registered.

## 10 SIDE EFFECTS AND CONTRAINDICATIONS

### 10.1 Side Effects

Please consult a doctor at once if you notice the following side effects:

- Sensation of a foreign body
- Build-up of earwax
- Skin irritation
- Dizziness
- Vomiting
- Headache
- Pain in or behind the ear
- Any subjective deterioration in your hearing or increase in the tinnitus level

### 10.2 Contraindications

Hearing aids should not be used under the following circumstances:

- Hearing loss due to mainly neural deficits
- Insufficient size/shape of the ear canal or malformations at the ear that do not allow for easy insertion and retrieval of the respective device.
- Adverse medical conditions of the outer ear and the ear canal e.g., chronic inflammations, chronic skin irritations, cholesteatoma
- Known allergies to any materials that have skin contact

Patients who are unable to operate the devices independently require competent assistance. The use of hearing aids for mentally impaired persons and for children should only be done on the recommendation of a doctor. A comprehensive risk assessment should be performed for the specific individual case. Close supervision by a caregiver is recommended to ensure proper use of the hearing instruments and to avoid accidental swallowing of hearing instruments or parts thereof.

## 11 OPERATING CONDITIONS

- Relative humidity between 10% and 90%
- Operating temperature between 0 °C and 40 °C
- Air pressure between 500 and 1060 hPa



## 12 TRANSPORT AND STORAGE CONDITIONS

- Relative humidity between 10% and 60%
- Storage temperature must lie between -20 °C and 60 °C
- Remove battery for storage
- Store away from magnetic fields

## 13 ENVIRONMENTALLY COMPATIBLE DISPOSAL

In accordance with European defaults used electrical and electronics devices may no more be given to the unsorted waste. The symbol of the waste bin on wheels refers to the necessity of separate collection. Please help with environmental protection and see to it that this device is given to the for this purpose designated systems of waste sorting if you do not use it any longer.

GUIDELINE 2012/19/EU of the EUROPEAN PARLIAMENT AND THE COUNCIL of July 04th 2012 about electrical and electronics old devices.

Alternatively, you can return your worn-out hearing aids and batteries to your hearing aid specialist for environmentally friendly disposal. He is your contact in the disposal chain for electronic waste.



## 14 OTHER INFORMATION


### EU declaration of conformity

audifon hereby declares that the products listed in this user manual comply with the following directive:

93/42/EEC for medical devices  
2011/65/EU RoHS for the reduction of hazardous substances.

The declaration of conformity can be viewed at

audifon GmbH & Co. KG  
Werner-von-Siemens-Straße 2  
D-99625 Kölldeda  
and at **[www.audifon.com](http://www.audifon.com)**

 All serious incidents involving the product that occur should be reported to the manufacturer and to the responsible authorities in the member state in which the user and/or the patient are registered.

## 15 SERVICE

Arrange for your hearing aids to be checked regularly by a hearing care professional.

\_\_\_\_\_

Date

\_\_\_\_\_

Hearing care professional

\_\_\_\_\_

Date

\_\_\_\_\_

Hearing care professional

\_\_\_\_\_

Date

\_\_\_\_\_

Hearing care professional

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Date

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Hearing care professional

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Date

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Hearing care professional

\_\_\_\_\_

Date

\_\_\_\_\_

Hearing care professional

## 16 KEY TO SYMBOLS



### Caution

Indicates a situation that may result in serious, moderate or minor injury.  
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



### Notice

Indicates possible damage to property.



### Information

Additional information for better understanding of the device.



### Manufacturer

Indicates the medical device manufacturer, as defined in the EU Medical Devices Regulation (EU) 2017/745 and in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.



### Date of manufacture

Indicates the date when the medical device was manufactured.



### Electronic waste (WEEE)

Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal.  
Dispose of properly, do not dispose of with household waste.



### Follow instructions

Follow the operating instructions.



### Humidity limitation

Indicates the range of humidity to which the medical device can be safely exposed.



### Temperature limit

Indicates the temperature limits to which the medical device can be safely exposed.



### Medical device

Indicates the item is a medical device



### Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



### Serial number

Indicates the manufacturer's serial number so that a specific medical device can be identified.



### Lot number, batch code

Indicates the manufacturer's batch code so that the batch or lot can be identified.




### CE mark

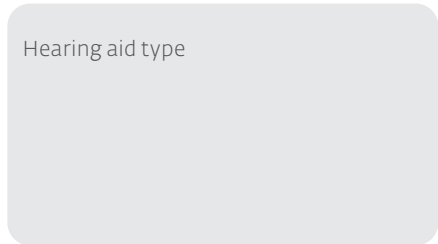
The device complies with all required EU regulations and directives.  
The four digit number indicates the identification of the notified body.

# WARRANTY CARD

You have chosen high-quality hearing aids from audifon.  
Your hearing care professional offers a \_\_\_\_\_ month warranty on our hearing aids from the date of purchase (date of invoice). The warranty covers defects in materials and manufacture. It does not cover batteries, chemical or electrochemical effects, wear and tear or mechanical damage due to improper handling. The right to claim under warranty is voided if you or any unauthorised third persons perform modifications or improper repair. Therefore please always follow the safety and care instructions. Proof of purchase must be provided as proof of warranty. The date of purchase and the serial number must be clearly visible. Warranty obligations will not result in any extension of the warranty period, nor will they give rise to a new warranty period for the hearing aid.

 The warranty period for built-in spare parts ends at the same time as the warranty period for the entire hearing aid.

Hearing aid type



\_\_\_\_\_  
Date of sale                      Your hearing care professional

\_\_\_\_\_  
Signature                      Stamp:

Name \_\_\_\_\_

No., street \_\_\_\_\_

Town, postcode \_\_\_\_\_

Telephone \_\_\_\_\_

Date of issue \_\_\_\_\_

**R**

Type \_\_\_\_\_ Side \_\_\_\_\_

Serial number \_\_\_\_\_

Warranty \_\_\_\_\_ Battery type \_\_\_\_\_

**L**

Type \_\_\_\_\_ Side \_\_\_\_\_

Serial number \_\_\_\_\_

Warranty \_\_\_\_\_ Battery type \_\_\_\_\_

# audifon



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