

HARMONIX

EN

Elevate Series

Self-tuned Hearing Aids

FDA 510k and CE approved



Instruction Manual

H205-BLK

H206-WHI

CONTENTS

1. GET TO KNOW YOUR DEVICE

- 1.1 Hearing Aids
- 1.2 Charging Case
- 1.3 Hearing Aid Markings

2. ACCESSORIES

3. USING THE HEARING AIDS

- 3.1 Fitting ear tips
- 3.2 ON/OFF
- 3.3 Wear/Remove hearing aids
- 3.4 Instruction for insertion depth
- 3.5 How to change the wax guard
- 3.6 Volume control
- 3.7 Programs switching
- 3.8 Bluetooth
- 3.9 How to use app
- 3.10 Hearing testing

4. USING THE CHARGER

- 4.1 Charging the hearing aids
- 4.2 Charging the charging case

5. HOW TO CARE FOR YOUR DEVICES

6. FURTHER INFORMATION

- 6.1 Troubleshooting
- 6.2 Charging case fault self-checking table

7. Technical specifications

8. Regulatory and legal information

9. Normalized symbols

10. Maintenance, cleaning, storage, and disposal

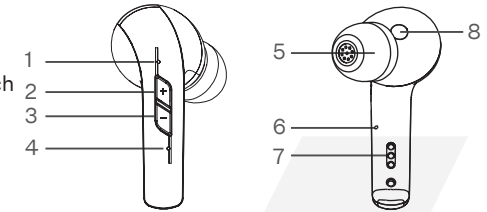
11. Warranty

12. Warnings

Part 1. Getting to know your device

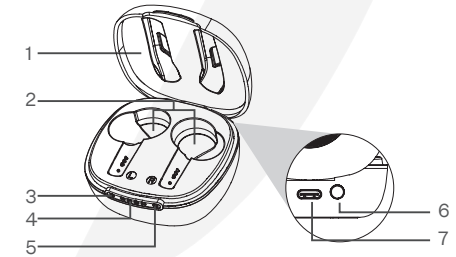
1.1 Hearing Aids – the buds

- 1. Microphone
- 2. Volume Increase / Hearing Program Switch
- 3. Volume Decrease
- 4. Microphone
- 5. Ear Tip
- 6. Microphone
- 7. Charging Contact
- 8. In-Ear Detection Sensor



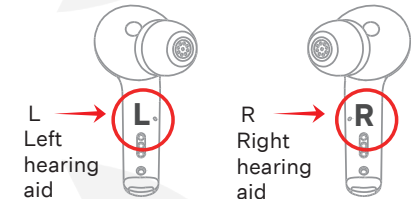
1.2 Charging Case

- 1. Upper Lid
- 2. Charging Slots
- 3. Indicator light for Left hearing aid
- 4. Indicator light for charging case
- 5. Indicator light for Right hearing aid
- 6. Power Switch for the charging case
- 7. USB-C Charging Port



3. Earbud Markings

There are markings on the underside of each earbud, which helps distinguish between left and right hearing aids



Part 2. Accessories

Item	Description
Ear tip x 6	Available in different sizes they provide a seal within the ear canal and hold the hearing aid securely in the ear
USB Cable x 1	Used to charge the charging case and hearing aids
Cleaning Tool x 1	Used to clean the hearing aids and charging cas
Instructions For Use x 1	Used for users to learn and understand how to use the hearing aids
Quick Start Guide x 1	A shortened version for more experienced hearing aid users

Part 3. Using the Hearing Aids

3a. Fitting Ear Tips

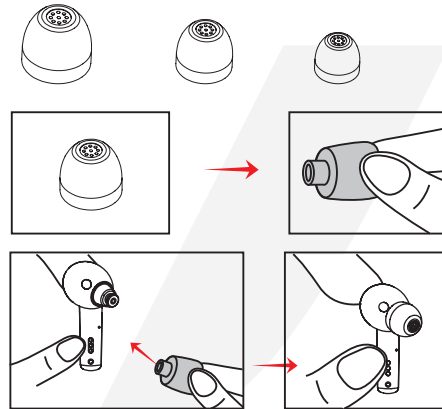
Please follow the following steps to apply ear tips to the hearing aids. Choosing the correct is vital to ensure a good seal to allow the hearing aid to work correctly. If the tip is too loose the hearing aid will fall out and create a whistling sound.

Step 1: Choose a suitable size of ear tip.

Step 2: Gently pull the rim membrane outwards

Step 3: Hold on the end of the hearing aid and push firmly to ensure that the ear tips are fastened securely

Step 4: Place each hearing aid in your ears and insert into the ear. Gently pull the hearing aid and it should remain in the ear. Make sure you test each ear as your ears can be slightly different in size.



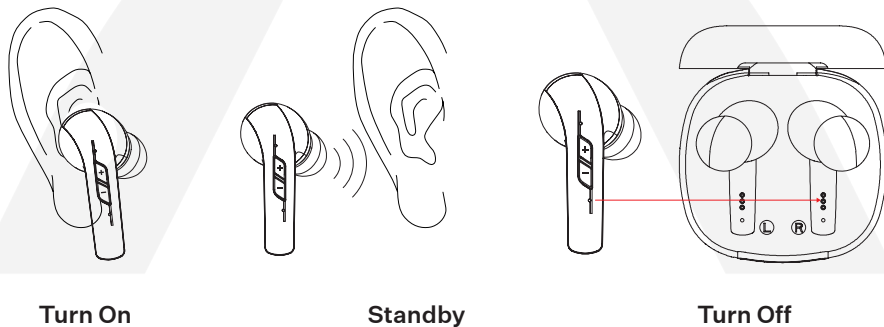
3b. Turning On and Off

Turn On

The hearing aids will turn on automatically when they are worn correctly. You will hear prompt tone "Power on".

Turn Off

The hearing aids will enter standby status automatically when they are removed from your ear. When you place the hearing aids back into the charging case, they will turn off automatically and give out prompt tone "Power off".



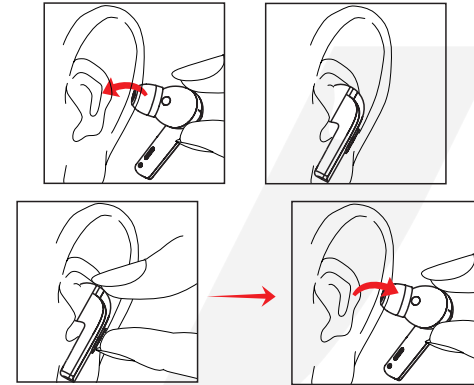
3c. Wearing / Removing Hearing Aids

- Your hearing aids are equipped with in-ear detection sensor.
- The hearing aids will enter the standby status automatically when removed from your ear.
- The hearing aids will turn on automatically when placed back in your ear.

Wearing Hearing Aids

Step 1: Hold the hearing aid and place it in your right or left ear.

Step 2: Move the hearing aid slightly in your auricle (ear) to promote a good fit



Removing Hearing Aids

Step 1: Grasp the hearing aid and remove it from your auricle gently.

Notice:

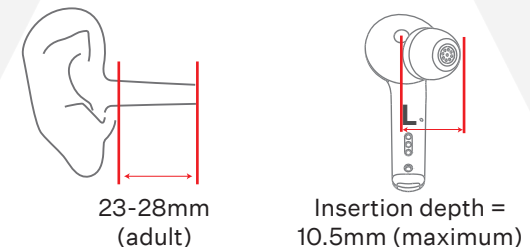
- Hearing aids will whistle when inserted incorrectly. Reinserting them into your ear canal correctly.
- If whistling remains after reinsertion, replace the ear tips with bigger size and try it again.
- If the hearing aids doesn't work properly, please check the "6.1 Troubleshooting". If none of the solutions works, contact our service team.

Part 3.4 Instruction for insertion depth

For adults, the average length of the ear canal has been estimated to be 23-28mm and the maximum insertion size of the hearing aid is 10.5mm.

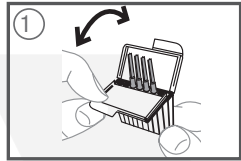
So, the distance from the ear tip to the tympanic membrane after wearing the hearing aid is at least 12.5mm, which is greater than the lower limit of 10mm specified by OTC.

Therefore, the device is safe and complies with OTC regulations.

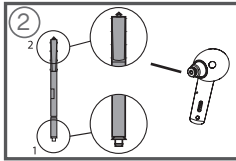


3e. How to change the wax guard

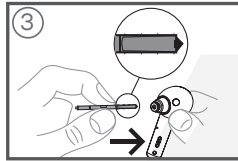
- Wax guard helps to protect the hearing aids from earwax.
- Wax guard is a disposable good that should be thrown away after used.
- The manufacturer does NOT supply additional wax guards with your hearing aids. If you need it, please buy it from your healthcare professional or somewhere else.
- Please follow the following steps to change the wax guard.



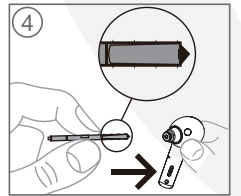
1. Open the Wax Guard Case as illustrated



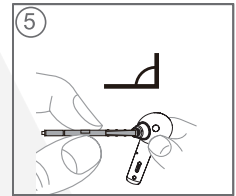
2. Take out the ear wax baffle



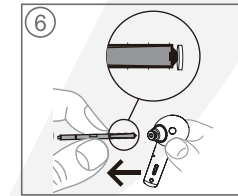
3. Hearing Aid wax guard position



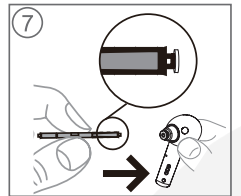
4. Insert the removal hook into the used wax guard.



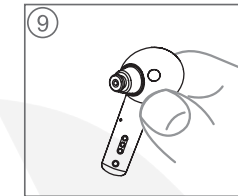
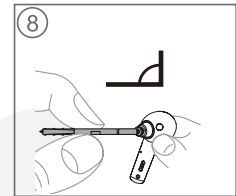
5. Keep the holder at a right angle.



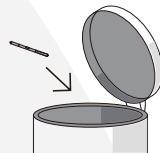
6. Pull the used wax guard straight out.



7-9. Insert the new wax guard into the opening of the sound outlet and press it gently and pull the holder straight out.



- Throw away the used wax guard
- If the wax guard cannot be locked on the hearing aids please replace the new wax guard

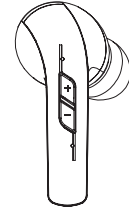


Part 3.6 Volume Control

The hearing aids have six(6) volume levels.

Short press the "+" button to increase the volume

Short press the "-" button to decrease the volume



Volume Level	Voice Tone
1	Volume 1
2	Volume 2
3	Volume 3
4	Volume 4
5	Volume 5
6	Maximum Volume

Part 3.7. Switching Programs

There are four (4) preset programs in the hearing aids. You could switch the hearing programs by long pressing the "+" button. Different programs have different beeps as below.

Hearing Program	Voice Tone
1	Program 1
2	Program 2
3	Program 3
4	Program 4

The hearing aids are designed with the memory function: The last setting can be remembered when the hearing aids

Part 3.8 Bluetooth

Bluetooth® is a registered trademark owned by the Bluetooth SIG, Inc. and any use of such marks by JINGHAO is under license.

Be sure Bluetooth is available on your phone.

Step 1: Turn on your hearing aids before connecting Bluetooth.

Step 2: Check the Bluetooth setting on your phone to “Pair New Device”.

Step 3: Select device name “Harmonix Elevate” to pair (connect) the Bluetooth of your phone.

Connection Status	Voice Tone
Connect Successfully	Connected
Disconnect	Disconnected

Accept any prompts given by your phone regarding Bluetooth connection.

Notice: Once the first pairing is done, the hearing aids will reconnect with your phone automatically if the Bluetooth of your phone is available.

Attention: Do NOT use the Bluetooth function of your hearing aids for any medical purposes.

Bluetooth Function description

(i) Listening to music

Increase the music volume by short pressing button “+” once.
Decrease the music volume by short pressing button “-” once.

(ii) Phone calls

Answer the incoming call by short pressing the button “-” once.
Reject the incoming phone or hang up the phone call by pressing the button “-” for about 1.5 seconds.

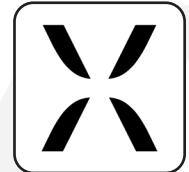
Part 3.9 Harmonix OTC App

How to Use the App

Read all the information before using the APP. A larger font printable booklet version of these instructions in multiple languages is available via our customer service site at harmonix.is/customerservice

Harmonix OTC App

Step 1: Tap to start “App Store” or “Google Play Store” on a compatible Apple or Android device.



Harmonix OTC

Step 2: Search “Harmonix OTC”.

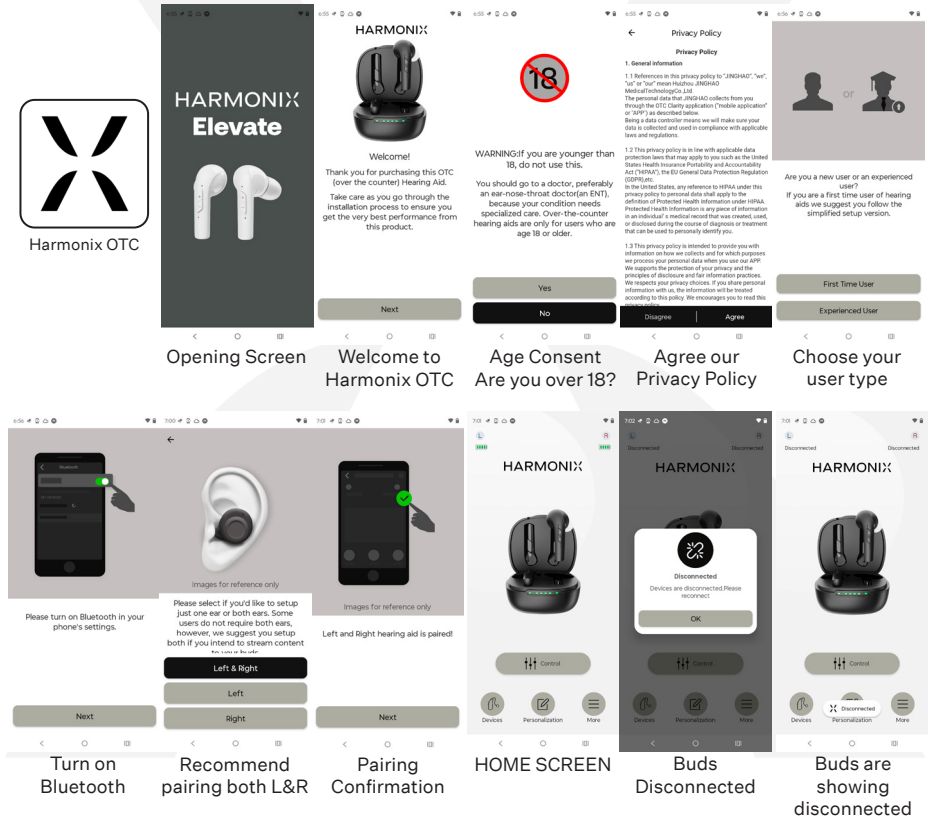
Step 3: Tap “GET” to download the “Harmonix OTC” APP.

Follow the system prompts to finish the installation.

Step 4: Tap to start the “Harmonix OTC” APP.

Step 5: Follow the novice guide to finish the setup.

Step 6: Start to personalize and fine-tune your hearing aid.



Further instruction is available on Harmonix OTC APP (“More Help”).

Requirement for running the app: iOS 14 or later; Android 5.0 or later.

iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries.

iOS is a trademark of Cisco Inc.

Android™ is a trademark of Google Inc.

harmonix.is
harmonixhearing.com

HARMONIX

harmonix.is
harmonixhearing.com

HARMONIX

Part 3.10 Hearing Testing

Welcome to use hearing aid and Harmonix OTC APP. This app allows you to perform a complete hearing test with your compatible hearing aids. The APP will automatically configure the hearing aids based on the results of your hearing test.

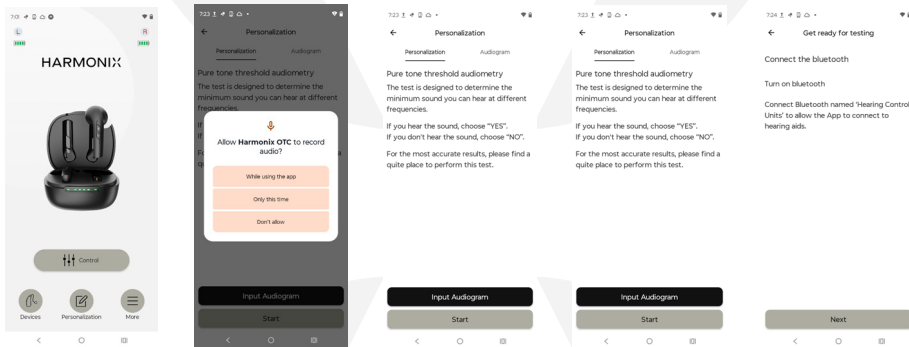
Connect the hearing aids

- While wearing the hearing aids have your Mobile phone ready and ensure that the Bluetooth function on the phone's system settings is connected to the hearing aids.
- Enter the "Bluetooth Devices" page from the homepage of the APP and connect to both the left and right hearing aids.

Find a quiet environment in which to perform the test

The APP will automatically detect the base noise level of the surrounding environment. If the ambient noise level is too high, the hearing test cannot be performed, and the APP will not proceed to the next step. Please find a quiet environment to continue (Figure 1).

We will test your hearing at six frequency points (measured in Hertz): 250, 500, 1k, 2k, 4k, 6k, choose "Yes" or "No" according to whether you can hear the tone or not. If you make an incorrect choice, you can go back a step by pressing "Undo" (Figure 2).



HOME SCREEN

Press on Personalise

ALLOW RECORDING

Press "While using the app" or "Only this time"

Input Audiogram/ Start

If you already have hearing aid data press Input Audiogram

Input Audiogram/ Start

If this is your first time use then press START

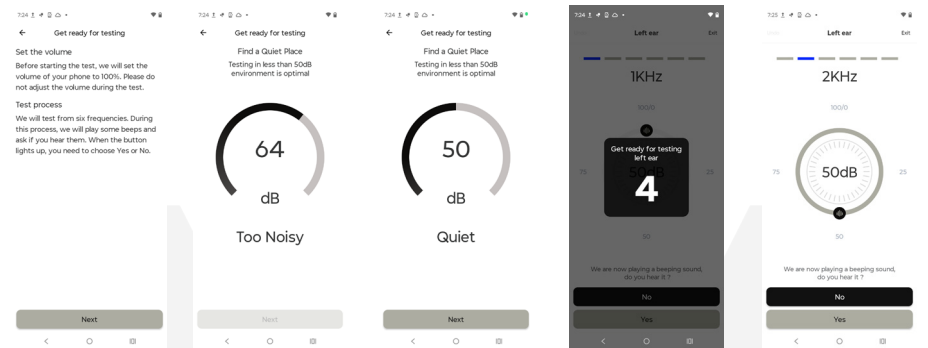
Get ready for testing

Make sure your hearing aids are connected

Save and set automatically

After completing the hearing test, the app will auto-fitting your hearing aids according to your hearing test result.

Part 3.10 Hearing Testing



Auto Volume

The APP will raise the volume to 100% - do not change this during the test

FIND A QUIET SPACE

The test is only possible if it is quiet

FIND A QUIET SPACE

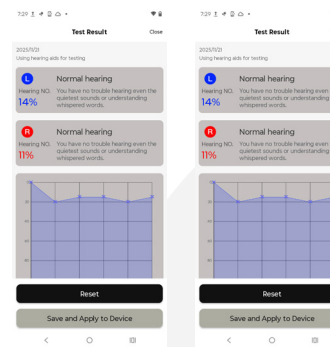
When you find that place the APP will allow the test to begin Press "Next"

5 Second Countdown

The test will play tones, once you hear the tone press "yes" otherwise press "no"

6 Frequencies per ear

The test will run in 10dB increments and then double check at 5dB



TEST COMPLETE

The APP will automatically save your test but please press SAVE AND APPLY TO DEVICE

RETAKE THE TEST

If you feel the environment changed or you wish to retake the test press "RESET"

Advanced Self Tuning Test

Your Harmonix Elevate Hearing Aid offers personalised tuning to your hearing for each ear. This is unlike cheaper multi environment hearing aids.

The benefit is that we use our AI App to determine what frequencies you cannot quite hear and adjust the output of our hearing aids to mirror this.

As a result, you will start to hear sounds you didn't hear before in greater clarity.

This is a significant step forward against non-tuned items.

We believe that your self-tuned hearing will offer a considerable improvement in enjoying life, participating where you would chose not to before and have a significant positive impact to your mental health.

This test is considered a medical grade test and these products are both US FDA 510k approved and CE approved in Europe.

Part 4: Using the Charger

Charging the Hearing Aids

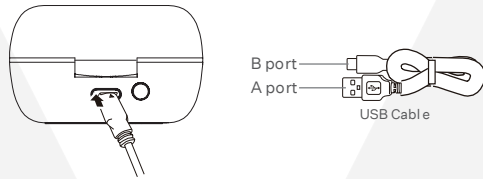
The hearing aids will turn off and start charging automatically when placed back into the correct slot of the charging case.

The blue indicator lights indicate that the hearing aids are charging and the white indicator lights indicate that the hearing aids are fully charged.

Charging the Charging Case

Step 1 : Connect the B port of the USB cable to the charging port of the charging case.

Step 2 : Connect the A port of the USB cable to the power supply.



Device	Working when	Charging State	Charging Indicator of the charging case
Hearing Aids	Hearing Aids are back in the charging case	Charging	Blue Solid Light
		Fully Charged	White Solid Light (automatically shuts off after 5 minutes)
Charging Case	Hearing Aids are back in the charging case and unplugged from USB power cable	100%	
		75% - 99%	
		50% - 74%	
		25% - 49%	
		0 - 24%	
	The charging case is charging via the USB power cable	100%	
		75% - 99%	
		50% - 74%	
		25% - 49%	
		0 - 24%	

Charging Indications of the Charging Case

Note: When the power level of the hearing aid is too low, the hearing aid will give out prompt tone. This indicates that the current hearing aid power is about to run out, please recharge it in time.

Part 5: Care Instructions

- Please follow the advice below for the best user experience and to prolong the life of your devices.
- Do not drop your hearing aids or knock them against hard surfaces.
- Do not use sharp tools to dislodge ear wax. Sticking household items into your devices can seriously damage them.
- Keep your devices away from high-temperature and/or high-humidity atmosphere.
- Do not swim, shower or sauna while wearing the hearing aids.
- Do not attempt to dry the hearing aids or charging case in an oven, microwave or other heating equipment. This will cause them to melt and may cause burns to your skin.
- Always remove your hearing aids when using hair care products. The hearing aids can become clogged and cease to function properly.
- Store your devices in a clean and dry location
- Do not use the electronic dryer to store the rechargeable hearing aids.
- Inspect the hearing aids, ear tips and charging case regularly. Remove earwax and debris from your devices by using enclosed cleaning tools.
- Clean the charging contacts of the rechargeable hearing aids with cleaning cloth regularly to ensure the normal charging.
- Ear tips should be replaced every 3-6 months or when they become stiff, brittle, or discoloured.

Part 6: Further Information

Hearing Aid Fault Self Check Table

Issue	Possible Causes	Potential Solution
No Sound	The Hearing Aids have not turned on	Turn on your hearing by putting back in the case and removing from charge
	The batteries are out of charge	Charge the hearing aids
	Speaker hole is blocked	Clear debris or ear wax from the speaker port
Voice is weak or fuzzy	Low Battery	Charge the Hearing Aids
	Volume is too low	Increase the volume
	Microphone is clogged	Clean debris or wax from the Hearing Aids
Hearing Aids cannot connect	The Bluetooth cannot connect automatically or by pressing the pre-connected device	Disconnect or remove the hearing aid and reconnect the Hearing Aids again
	Bluetooth Function is turned off	Ensure that Bluetooth is turned on

Hearing Aid Fault Self Check Table (cont)

Issue	Possible Causes	Potential Solution
Scan or search of the Hearing Aids via Bluetooth is unsuccessful	Hearing Aids are connected to another device	Disconnect from another device and reconnect again
Cannot operate and adjust the Hearing Aids via the APP after connecting successfully	Hearing Aids are not actually connected to the APP	Reconnect the Hearing Aids
Music of phone function is not working after successfully connecting	The Hearing Aids have not been given permission to access the functions	Go to Permissions in the settings and ensure that the Harmonix OTC App is permitted to connect to phone functions
	Do-Not-Disturb mode on your device is enabled	Turn off 'Do-not-disturb' in the phone settings

Charging Case Self Check Table

Issue	Possible Causes	Potential Solution
Indicator light on the charging case is not lighting up or flashing	USB Cable is not supplying power	Reconnect the cable to the source or replace the cable
	Charging Case is not connected correctly to the cable	Refit the cable
	Battery is out of charge	Recharge the case fully
Hearing Aids are not charging in the case	Hearing Aids are not inserted into the correct slot	Reinsert the hearing aids in the correct side
	Charging contacts are dirty	Clean the charging contacts on both the hearing aids and the charging case

Part 7: Technical Information

Test Standard: ANSI 3.22-2014
 Test Equipment: FONIX 8000
 Test Coupler: 2CC HA-1

OTC Hearing Aid Technical Specifications	
Test Item	Value
Maximum Output (OSPL90)	112 dB
HFA-full-on gain (HFA-FOG)	25 dB
Latency Value	6 ms
Total Harmonic Distortion Value (THD)	3%
Frequency Response Bandwidth	F1= 200Hz F2=5500Hz
Frequency Response Smoothness	6 dB
Operating Conditions	Temperature: 0°C~40°C, Relative humidity: 30%-75%RH, Atmospheric pressure range: 86 ~ 106kPa
Storage and Transportation	Temperature: -10°C~+55°C, Relative humidity: 10%-90%, Atmospheric pressure range: 70 - 106kPa
Battery Life	
Test Items	Duration
Hearing Aid when Bluetooth is disconnected	>12 hrs

Actual Battery life depends on the state of the battery, usage pattern, active feature set, hearing loss levels and sound environments

The data contained in packaging and in this guide are sourced from laboratory conditions and may not represent or guarantee values.

Part 8: Regulatory and Legal Information

- This part applies to the product with Bluetooth or APP function.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
- This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

Part 8: Regulatory and Legal Information (cont.)

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by manufacturer could void the user's authority to operate this equipment.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This device complies with FCC radiation exposure limits set forth for general population. This transmitter must not be located or operating in conjunction with any other antenna or transmitter.
- FCC ID: 2A39M-JH22A61H
- Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.
- Radio Transceiver Frequency Range: 2.4 to 2.480 GHz
- Radio Receiver Bandwidth: 2MHz.
- Modulation Type: 1 Mb/s GFSK Peak Effective Isotropic
- Radiated Power: 0 dBm.
- This equipment has been tested and found to comply with the limits per CISPR 11 class B.

Important Information regarding Electro Magnetic Compatibility (EMC)

- With the increased number of electronic devices such as PC and mobile (cellular) telephones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, Medical devices in use may be susceptible to electromagnetic interference from other device. Electromagnetic interference may result in incorrect operation of the medical devices and create a potentially unsafe situation. Medical devices should also not interfere with other devices.
- In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices.
- This unit has been thoroughly tested and inspected to assure proper performance and operation! This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, the following tables recommend minimum separation distances between portable and mobile RF communications equipment and the RJADAT-1 unit.

Guidance and manufacturers Declaration of Electromagnetic emissions for all EQUIPMENT and SETTINGS


Guidance and manufacturers Declaration of Electromagnetic emissions			
Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.			
Emission Test	Classified / Test Level	Compliance	Electromagnetic Environment - Guidance
Power Line conducted emission test	CISPR 11, Class B, Group 1	N/A	Hearing Aids use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and manufacturers Declaration of Electromagnetic emissions			
Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.			
Emission Test	Classified / Test Level	Compliance	Electromagnetic Environment - Guidance
Radiated emission test	CISPR 11, Class B, Group 1	Pass	The Hearing Aids are suitable for use in all establishments, other domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emission test	IEC 61000-3-2, Class A	N/A	
Voltage fluctuations and flicker emissions	IEC 61000-3-3	N/A	

Guidance and manufacturers Declaration of Electromagnetic emissions for all EQUIPMENT and SETTINGS

Guidance and manufacturers Declaration of Electromagnetic emissions		
Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.		
Immunity Test	IEC 60601 test level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Radiated RF electromagnetic fields immunity test	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band (IEC 60601-1-2:2014+A1:2020 section 8.10 table 9)	10V/m,80MHz -2.7GHz 80% AM at 1KHz RF Band (IEC 60601-1-2:2014+A1:2020 section 8.10 table 9)
Electrical fast transient and burst test IEC 61000-4-4	AC port: ±2 kV Patient coupling port: ±1 kV 100kHz repetition frequency	N/A
Surge test IEC 61000-4-5	Line to line: ±500V, 1kV Line to ground: ±500V,±1kV,±2 kV	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m, 50Hz and 60Hz	N/A
Voltage dips, and interruption IEC 61000-4-11	0% UT± 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	N/A
	0% UT± 1cycle and 70% UT; 25 cycles Single phase: at 0°	
	0% UT± 250 cycles	
Proximity magnetic fields immunity test	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11	IEC 60601-1-2: 2014+A1:2020 section 8.11 table 11
NOTE: UT is the a.c. mains voltage prior to the application of the test level		

Guidance and manufacturers Declaration of Electromagnetic Immunity for equipment and systems that are not life supporting

Guidance and manufacturers Declaration of Electromagnetic Immunity for equipment and systems that are not life supporting		
Hearing aids are intended for use in the electromagnetic environment specified below. The customer of the user of hearing aids should assure that it is used in such an environment.		
Immunity Test	Conducted RF IEC 61000-4-6	Radiated RF IEC 61000-4-3
IEC 60601 test level	10 Vrms 150 kHz to 80 MHz	10V/m 80 MHz to 2.5 GHz
Compliance Level	10 Vrms	10V/m 80 MHz to 2.5 GHz
Electromagnetic Environment Guidance	<p>Portable and Mobile RF communications equipment should be used no closer to any part of hearing aid treatment device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommendation separation distance</p> $D=1.2\sqrt{P}$ $D=1.2\sqrt{P} \text{ 80MHz to 800MHz}$ $D=2.3\sqrt{P} \text{ 800MHz to 2.5 GHz}$ <p>Where P is the maximum output power rating of the transmitter manufacturer and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol. </p>	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
 Note 2: These guidelines may not affect all situations, Electro-Magnetic propagation is affected by the absorption and reflection from structures, objects and people.
 (a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which hearing aids are used exceeds the applicable RF compliance level above, hearing aids should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating hearing aids.
 (b) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.















Part 9: Normalized Symbols

Recommended separation distances between portable and mobile RF communications			
Hearing aids are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of hearing aids can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and hearing aids as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

	Follow operating instructions		
	B type applied part		
	Disposal in accordance with Directive 2012/19/EU (WEEE)		
	Date of manufacture		Manufacturer information
	Serial Number		USE By
	Warning/Danger: Improper use may cause serious injury or death		
	Medical Device		
	Permissible storage and transport temperature and humidity		
	Permissible operating temperature and humidity		
	Permissible storage and transport temperature and humidity		Comply with Directive 2011/65/EU
	Paper Packaging Recycling		

Notes: This hearing aid is produced under the strict quality system of Huizhou JINGHAO Medical Technology Co.,Ltd. and Harmonix ehf.

The device complies with the IEC 60601-1 standard.

Part 10. Maintenance, Cleaning, Storage and Disposal

Maintenance

- 1) We do not authorize any institution or individual to maintain and/or repair the product. If you suspect that the products may be in question, please contact us immediately.
- 2) The user must not attempt any repairs to the device or any of its accessories. Please contact us for any repair needs.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty. Warning : No modification of this equipment is permitted.

Cleaning

- 1) Cleaning the ear tips -Remove any earwax buildup using the clean stick. Wipe clean with a tissue or soft cloth.
- 2) Cleaning hearing aids - Use a soft cloth or tissue to wipe any moisture, perspiration, or debris from the surface of the hearing aids.

Note: Do not use alcohol or other cleaning solvents to clean the hearing aids as this could damage the protective covering.

Storage

- 1) Always store your rechargeable devices in the Charging Case when not in use.
- 2) Do not store or expose the devices and/or case to extreme hot/cold temperatures, moist/humid environments, or shock/vibration.
- 3) The hearing aids should be fully charged before using for the first time. Do not store the hearing aids for extended periods of time without recharging them (max. six months).

Disposal

Please dispose of the device in accordance with the directive 2012/19/EU-WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please refer to your local authority responsible for waste disposal.

WARRANTY

US Limited Warranty

This limited warranty covers defects in material and workmanship for a period of one (1) year from the date of purchase, which includes the hearing devices, charger case, and cord within the warranty period. Proof of purchase (receipt) is required to prove ownership.

EU Limited Warranty

This limited warranty covers defects in material and workmanship for a period of two (2) years from the date of purchase, which includes the hearing devices, charger case, and cord within the warranty period. Proof of purchase (receipt) is required to prove ownership.

Any damage caused by improper handling and care, exposure to elements or chemicals, or unauthorized service will not be covered by the warranty. All other damage claims excluded. A warranty claim must be submitted with the purchase receipt.

Contact Harmonix customer service in the event of failure.

www.harmonix.is/customerservice.

Manufactured by Huizhou Jinghao Medical Technology Co., Ltd.

Address: No. 207, South SiHuan Rd,
ZhongKai Hi-tech District, Huizhou,
Guangdong, China.

Tel: +86-752-2266961

Website: <http://www.jhhearingaids.com>



harmonix.is
harmonixhearing.com

PART 11: Warnings

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-Counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older.

People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

WARNING: When to see a doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

WARNING: do not use if any of the followings apply to you:

Congenital atresia of external ear or deformity of any part of the ear canal

- Deafness is unstable, and the degree of hearing loss often fluctuates
- Persistent headaches, dizziness, earaches, tinnitus or other symptoms that are not suitable for adaptation
- Sudden onset of hearing loss within the past 3 months;
 - rapid progressive deafness;
 - unilateral hearing loss or
 - other acute ear disease
- Effusion (secretions/discharge) in the ear and/or frequent purulence (pus).
- Central deafness (central nervous system) or non-organic deafness.
- Patients with acute otitis externa and tympanitis.
- Patients with acute and chronic suppurative otitis media (in the period of purulent infection).
- Patients who are allergic to the materials of this product.

HARMONIX

harmonix.is
harmonixhearing.com

HARMONIX

WARNING: Important Safety Instruction

- Keep small parts (hearing instrument, ear tips, battery or other detachable parts) that can be swallowed out of children's reach.
- Dropping, immersing in liquid, exposure to strong electromagnetic fields or excessive heat will damage the hearing aid. Remove devices prior to any type of X-ray, MRI, or CT scan.
- If parts become stuck in the ear canal, seek medical assistance-do not attempt to remove by yourself.
- Do not use at high volume for extended periods of time - ear injury can result.
- If you experience any pain or strong discomfort using the devices, remove and consult a doctor.
- Routine maintenance to keep the device clean is required. Ensure that ear tips are always free of debris and moisture.
- Do not store or use the product in environments of high humidity or temperature (such as sauna room), to avoid damage.
- Batteries should be properly recycled and not disposed in the trash.
- Keep the devices away from children. Injury or damage may result.
- Do not share your hearing aids with others. Using a hearing aid configured for someone else can result in hearing damage or injury.
- Monitor for any unusual skin reaction. If you notice any allergic reaction (itchiness, swelling, or rash), stop wearing the hearing aids and consult a medical specialist.
- Stay away from strong electromagnetic fields when using hearing aid to avoid unexpected damage. Your hearing aids are delicate electronic instruments and may be damaged by contact with strong magnetic equipment such as electromagnetic ovens, microwave ovens, ultrasonic cleaners, etc.
- If the Bluetooth function is available for your device, do NOT connect the hearing aid and headsets to the mobile phone via Bluetooth simultaneously -noise, distortion or any other unexpected problems may occur to your hearing aid.

Please contact the MANUFACTURER: For assistance, if needed, in setting up, using or maintaining your devices or to report any unexpected operation or events.

- Contact your hearing professional for assistance if needed.
- Do NOT fix your devices by yourself. Doing so will not only void the warranty but also cause further damage easily - Check the "Troubleshooting" first when failures occur to your devices.

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss. People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counselling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc. Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

Note: If you experience side effects, contact a hearing care professional.

Possible side effects from wearing the hearing aid may be:

- Dizziness
- Tinnitus
- Perceived worsening of hearing loss
- Nausea
- Headache
- Skin reaction
- Excessive ear wax accumulation

Note: Tips for better communication

It will take practice, time, and patience for your brain to adapt to the new sounds that your hearing aids provide. Hearing is only part of how we share thoughts, ideas and feelings. Reading lips, facial expressions, and gestures can help the learning process and add to what amplification alone may miss.

(1) Please review the following simple communication tips for you:

- Move closer to and look at the speaker.
- Sit face-to-face in a quiet room if possible.
- Try out different locations to find the optimal places to listen
- Minimize distractions.
- Background noises may be frustrating at first; remember, you have not heard them for a while.
- Let others know what you need; keep in mind that people cannot “see” your hearing loss.
- Develop realistic expectations of what your hearing aids can and cannot do.
- Better hearing with hearing aids are a learned skill combining desire, practice, and patience.

(2) You will learn and adjust, it just takes a little time. Remember to be patient with yourself and the hearing aids.

(3) For Your Family and Friends: Your family and friends are also affected by your hearing loss.

Request that they:

- Get your full attention before beginning to speak.
- Look at you or sit face-to-face.
- Speak clearly and at a normal rate and level; shouting can actually, make understanding more difficult.
- Rephrase rather than repeat the same words; different words may be easier to understand.
- Minimize distractions while speaking.

Additional cautions:

- The use of accessories and cables other than those specified by manufacturer, except for cables sold by manufacturer as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- Do not bring the device into any MRI, CT, diathermy, RFID and electromagnetic security systems such as metal detectors environment or near any of this equipment. Consult manufacturer if you have any questions.
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used

There is no guarantee that interference will not occur in a particular installation. Radiated or conducted electromagnetic signals can cause:

1) As to devices:

- Deviation of the values of pulse duration, amplitudes, and repetition frequencies, may impair the unit’s essential performance. The device has passed EMC highest interference level test, and the parameters do not deviate the essential performance requirement.
- The device displays abnormally.

2) As to patients:

- The sensitivity of stimulation may be weaker or stronger, but it does not produce safety issues.
 - It cannot achieve expected effect.
- If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:
- If feeling too weak or too strong stimulation, adjust the strength level to an acceptable level.
 - If the device display is abnormal, power off and restart the device and check whether it shows properly.
 - Re-orient or re-locate the affected device.
 - Increase the separation between the unit and the affected device.
 - Power the equipment from a source other than that of the affected device.
 - Consult the service representative for further suggestions.

Intended use

The Self-Fitting hearing aids are a pair of user-fitted wireless air conduction hearing aids intended for use by person with perceived mild to moderate hearing impairment.

Contraindication

The device is unsuitable and should not be used in the following situations:

- (1) Patients with chronic suppurative otitis media, congenital ear atresia to banned use.
- (2) This hearing aids only be used for compensating the patients with hearing impairment, do not have hearing therapeutic value.

EU DECLARATION OF CONFORMITY

According to Annex IV of Regulation (EU) 2017/745

1. Manufacturer

Huizhou Jinghao Medical Technology Co., Ltd.

Floor 1st, 4th, 5th, 9th & 10th, No.1 Building
No. 207 South SiHuan Road
ZhongKai Hi-tech District
Huizhou City, Guangdong Province
China

Single Registration Number (SRN): **CN-MF-000020483**

2. EU Authorized Representative

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich
Germany

3. Device Identification

Product name: Elevate Hearing Aid (JH-32A)

Device type: Digital air-conduction hearing aid

Intended purpose:

A wearable electronic device intended to compensate for impaired hearing by amplifying sound signals and delivering them to the ear of the user.

Basic UDI-DI: 06971094538561

Model numbers: Elevate (H205-BLK, H206-WHI)

4. Device Classification

Classification	Description
Risk Class	Class IIa
Rule	MDR Annex VIII Rule 9
GMDN Code	34902 – Hearing aid, air conduction
EMDN Code	G10.03.01 – Hearing aids

Huizhou Jinghao Medical Technology Co., Ltd.

Floor 1st, 4th, 5th, 9th & 10th, No.1 Building
No. 207 South SiHuan Road
ZhongKai Hi-tech District
Huizhou City, Guangdong Province
China

5. Conformity Assessment Procedure

The conformity assessment procedure has been carried out according to:

Regulation (EU) 2017/745 on Medical Devices (MDR)

Annex IX – Quality Management System and Technical Documentation Assessment.

Notified Body:

SGS Belgium NV
Noorderlaan 87
2030 Antwerp
Belgium

Notified Body Number: **1639**

QMS Certificate Number: **CN24/00005770**

MDR Huizhou Jinghao_HZH15994_CT

6. Harmonised Standards Applied

The following standards have been applied where applicable:

- EN ISO 13485:2016 – Quality management systems for medical devices
- EN IEC 60601-1 – Medical electrical equipment – General requirements for safety
- EN IEC 60601-1-2 – Electromagnetic compatibility
- EN IEC 60118 series – Electroacoustics – Hearing aids
- EN ISO 14971 – Risk management for medical devices
- EN IEC 62366-1 – Usability engineering
- EN IEC 62304 – Medical device software lifecycle processes
- EN ISO 10993 series – Biological evaluation of medical devices

7. Declaration

We hereby declare under our sole responsibility that the medical device described above complies with the relevant provisions of:

Regulation (EU) 2017/745 on medical devices.

All supporting documentation is retained within the technical documentation of the manufacturer.

8. Place and Date of Issue

Huizhou, China

Date: 1st January 2026

9. Authorized Signatory

Name: Flora Xie

Title: Account Representative

For and on behalf of:

Huizhou Jinghao Medical Technology Co., Ltd.

Signature: *For and on behalf of*
Huizhou Jinghao Medical Technology CO.,LTD
惠州市锦好医疗科技股份有限公司

Flora Xie
.....
Authorized Signature(S)