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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-A32)
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:	0697109453DigitalV2.
UDI-DI code / Issuing entity	06971094538578 / GS1
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

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

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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: 24th June 2026

9. Authorized Signatory

Name: Flora Xie
Title: Account Representative
For and on behalf of:
Huizhou Jinghao Medical Technology Co., Ltd.

Signature:



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

EU DECLARATION OF CONFORMITY

Device Name: Hearing aid

Model: JH-A32

Revision History

No.	Date	Description of change	Version
1	2026.05.22	First issued	V1.0

Manufacturer	**Huizhou Jinghao Medical Technology Co., Ltd.** Floor 6, Huicheng Industry Building, No.9 Huifeng Dong'ER Road Road, Zhongkai High-tech Zone, Huizhou City, Guangdong Province, China
Device information	**Product name: Hearing aid** Trade name: Hearing aid Model: JH-A32
Description	Hearing amplifier

Applied Standard & Common Specification:

Document Number	**Title of Document**
EN 301 489-1 Ver. 2.2.3 (2019-11)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
EN 301 489-17 Ver. 3.2.4 (2020-09)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 300 328 V2.2.2 (2019-07)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

Conformity Statement:

We hereby declare that the above-mentioned product fully complies with the essential health, safety, electromagnetic compatibility and harmonized standards.
All relevant test reports including LVD safety report, EMC test report, RED wireless test report have been completed and kept in complete technical documents.
We take full responsibility for the conformity of this product. Technical construction files are available for inspection by relevant European official authorities.

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)

Authorized Signatory：_____ Date：1st June 2026

Position：Quality Manager / Legal Representative Place：Huizhou, China

EU Declaration of Conformity

Product	Elevate Hearing Aid
Model Numbers	H205-BLK, H206-WHI
Sku Number	JH-A32

Manufacturer	
Name:	Huizhou Jinghao Medical Technology Co., Ltd.
Address:	Floor 6, Huicheng Industry Building, No.9 Huifeng Dong'ER Road Road, Zhongkai High-tech Zone, Huizhou City, Guangdong Province
Country:	China

Authorised brand for use in the EU	
Name:	Harmonix ehf.
Address:	Reykjavikurvegi 64, 220 Hafnarfjordur,
Country	Iceland

This declaration of conformity is issued under the sole responsibility of the manufacturer