Declaration of Conformity CE 1639

Manufacturer:	**Huizhou Jinghao Medical Techology Co., Ltd.**
Manufacturer Address:	Floor 6, Huicheng Industry Building,No.9 Huifeng Dong'ER Road Road,Zhongkai High-tech Zone, Huizhou City, Guangdong Province, China
EC-Representative:	ShanghaiInternationalHolding Corp.GmbH(Europe)
EC-Representative address:	Eiffestrasse80,20537Hamburg,Germany
Product:	Hearing aid
Model:	JH-908（HA60） /JH-907/JH-906/JH-900A/JH-A17/JH-A39/JH-125/JH-113 /JH-117/JH-116/JH-115/JH-121/JH-138/JH-158/JH-180/JH-351/ JH-338/JH-339/JH-D101/JH-D16/JH-D18/JH-D19/JH-D03/ JH-D26（HA70）/HA75（HA85）/HA70（HA80）
Classification:	IIa (Rule 9)
Conformity Assessment Route:	MDD Annex V
DMDNS/UMDNS code:	**17253**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body: SGS Belgium NV Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

Notified Body No.: 1639

Certificate No.: CN19/41044

Start of CE-Marking: Dec– 2014

Place, Date of Issue: 4th-June-2020

Signature: .....

Name of Authorized Signatory:

Position Held in Company: General Manager

Applied Standards List

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No.	Standard	Standard Title
1	93/42/EEC amended by	Medical Devices Directive
2	2011/65/EU	On the restriction of the use of certain hazardous substances in electrical and
3	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
4	EN 1041:2008	Information supplied by the manufacturer
5	EN ISO 10993-1:2009/ AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
6	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO
7	EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin
8	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
9	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-
10	EN 60601-1-6:2010	Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (IEC 60601-1-6:2010)

11	IEC 60601-1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
12	EN 60118-13:2016	Electroacoustics - Hearing aids -Part 13: Electromagnetic compatibility (EMC)
13	IEC 60601-2-66: 2015	Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems.
14	IEC 60118-7:2005	Electroacoustics – Hearing aids Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes
15	EN 62366-1:2015	Medical devices – Application of usability engineering to medica devices
16	EN ISO 780:2015	Packaging. Distribution packaging. Graphical symbols for handling and storage of packages
17	ISTA-2A: 2011	Shipping mark, Description of package- product; Transportation test (include: vibration test, drop test, compression
Other applicable guides		
18	MEDDEV.2.7.1 Rev.4	Guidelines on Medical Devices Clinical evaluation: A guide for manufacturers and notified bodies
19	MEDDEV 2.12-1 Rev.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
20	MEDDEV 2.12-2 Rev.2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES：A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES