



EC Certificate Production Quality Assurance System: Certificate CN19/41044

The management system of

## Huizhou Jinghao Medical Technology Co., Ltd.

Floor 6, Huicheng Industry Building, No.9 Huifeng Dong'er Road,  
Zhongkai High tech Zone, Huizhou City, Guangdong Province, 516000, P.R. China  
has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC

on medical devices, Annex V

For the following products

**Compressor Nebulizer for Asthma Treatment on Conscious Patients**  
(Model: JH-102, JH-108, JH-109, JH-202, JH-103, JH-106, JH-208, JH-302, JH-209),  
**Hearing Aids**(Model: JH-115, JH-180, JH-906, JH-A17, JH-121, JH-338, JH-339,  
JH-D101, JH-D16, JH-D18, JH-D19, JH-D26, HA75, HA70, JH-113, JH-116, JH-117,  
JH-118, JH-119, JH-125, JH-129, JH-138, JH-158, JH-351, JH-900A, JH-907,  
JH-908, JH-D03, JH-D04, JH-A39, JH-A50, JH-D12, JH-D30, JH-D37, JH-D31, JH-D36,  
JH-D58, JH-D59, JH-D54, JH-A51, JH-W2, JH-W3, JH-W5, JH-W6)

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 02 June 2020 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.  
Issue 2. Certified since 15 December 2014  
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/HZH/ 15994

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 Annex V\_EN rev. 01

Page 1 of 1



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm). Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



# Certificate of Compliance

Certificate Number: DL-2018070985C

**Applicant:** Huizhou Jinghao Medical Technology Co., Ltd  
FL6, Huicheng Industry Bld, Zhongkai High-tech Zone, Huizhou, Guangdong, China

**Manufacturer:** Huizhou Jinghao Medical Technology Co., Ltd  
FL6, Huicheng Industry Bld, Zhongkai High-tech Zone, Huizhou, Guangdong, China

**Product:** Hearing aid

**M/N:** JH-115  
JH-125, JH-113, JH-117, JH-158, JH-138, JH-119, JH-129, JH-180, JH-116, JH-121,  
JH-301, JH-301O, JH-301R, JH-D10, JH-D03, JH-D04, JH-D04-1, JH-D16, JH-D18,  
JH-D19, JH-D20

**Test Standard:** EN 55014-1:2017  
EN 61000-3-2:2014, EN 61000-3-3:2013  
EN 55014-2:2015  
EN 61000-4-2:2009, EN 61000-4-3: 2006+A1:2008+A2:2010  
EN 61000-4-4:2012, EN 61000-4-5:2014  
EN 61000-4-6:2014, EN 61000-4-11:2004

The EUT described above has been tested by us with the listed standards and found in compliance with the council EMC directive 2014/30/EU. It is possible to use CE marking to demonstrate the compliance with this EMC Directive. It is only valid in connection with the test report number: DL-2018070985E.



This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.

DL Certification & Testing Co., Ltd.  
4F, Building B, No. 41, Guiping Road, Heao Community, Longgang District, Shenzhen, China.  
Web: www.dl-cert.com E-mail: Service@dl-cert.com Tel: 400-688-3552



Certificate CN14/31479

The management system of

## Huizhou Jinghao Medical Technology Co., Ltd.

Floor 6, Huicheng Industry Building, No. 9 Huifeng Dong'er Road, Zhongkai  
High-tech Zone, Huizhou City, Guangdong Province, 516000, P.R. China

has been assessed and certified as meeting the requirements of

### ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Manufacture of Compressor Nebulizers and Hearing Aids  
for medical use**

This certificate is valid from 19 March 2018 until 31 March 2019  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 5. Certified since 15 December 2014

Authorised by



SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

HC SGS 13485 2003 0118

Page 1 of 1



0005

