

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-D59, JH-D54, JH-W2, JH-W3, JH-W5, JH-W6)

Where the above scope includes class III 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

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 AnnexV_EN rev. 01

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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-3010, 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

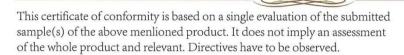
EN 61000-4-2:2009, EN 61000-4-3: 2006+A1:2008+A2:2010

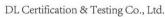
EN 61000-4-4:2012, EN 61000-4-5:2014 EN 61000-4-6:2014, EN 61000-4-11:2004

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: $DL_{\tau}2018070985E$.









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

HC.

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