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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 004906 0001 Rev. 00

Manufacturer:

**Changzhou Hengjie Medical
Devices Co., Ltd.**

3A, No.256 Middle Mingxin Road, Hutang
Wujin District
213164 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, THE
NETHERLANDS

**Product Category(ies): Metal Bone Plate (Straight and Irregular type),
Metal Bone Screw,
Metal Intramedullary Nail**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

SH18135001

Valid from:

2019-04-12

Valid until:

2024-04-11

Date,

2019-04-12

Stefan Preiß

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Facility(ies):

Changzhou Hengjie Medical Devices Co., Ltd.
3A, No.256 Middle Mingxin Road, Hutang, Wujin
District, 213164 Changzhou, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA

-/-



REGISTRATION NO. 04719Q10000687

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Changzhou Hengjie Medical Devices Co., Ltd.

Registered Address: Floor 1-3, #3A, No.256 Middle Mingxin Road, Wujin Tech Park, Gounan Industrial Zone, Hutang, Wujin District, Changzhou, China
Postcode: 213164

Manufacturing Address: 3A, NO.256 Middle Mingxin Road, Hutang Wujin District 213164 Changzhou, China

Has been assessed and conformed to the following standard(s)
YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of Metal Intramedullary Nail, Metal Bone Screw, Metal Bone plate (Straight and Irregular type), Spinal Screw Plate, Spinal Screw Rod System, Spinal Fusion System (Only for export).

Date of issue: April 08, 2019

Date of expiry: April 07, 2022

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993