



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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

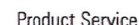
Valid until:

2024-04-11

Date,

2019-04-12

Stefan Preiß



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Facility(ies):

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District, 213164 Changzhou, Jiangsu, PEOPLE'S
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