



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 080430 0010 Rev. 01

Manufacturer:

**Changzhou Kanghui
Medical Innovation Co., Ltd.**

No. 11, North Changjiang Road
Xinbei Zone
213022 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**Sterile and Non-Sterile Lockable
Intramedullary Nails,
Bone Plates, Bone Screws,
General Spine System, Drill Bits,
Metal Bone Pins, Balloon Tube,
Vertebroplasty Instrument Kits,
Interbody Fusion Fixation System**

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.:

SH19108EXT01

Valid from:

2019-06-06

Valid until:

2024-05-26

Date,

2019-06-06

Stefan Preiß

Head of Certification/Notified Body



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Facility(ies):

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Jiangsu, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT