DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 080430 0012 Rev. 03

**Holder of Certificate:**

**Changzhou Kanghui Medical Innovation Co., Ltd.**
No. 11, North Changjiang Road
Xinbei Zone
213022 Changzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Changzhou Kanghui Medical Innovation Co., Ltd.
No. 11, North Changjiang Road, Xinbei Zone, 213022 Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Digitally signed by Axentii Olga
Date: 2021.06.07 15:20:40 EEST
Reason: MoldSign Signature
Location: Moldova

**Scope of Certificate:**

**Design and Development,
Production and Distribution of
Lockable Intramedullary Nails, Bone Plates,
Bone Screws and General Spine System,
Orthopaedic Instruments, Metal Bone Pins,
Balloon Tube, Interbody Fusion Fixation System
Production and Distribution of
Hip Joint System, Knee Joint System,
Instruments for Hip Joint System,
Instruments for Knee Joint System,
Depth Gauge, Radiographic Ruler**

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 080430 0012 Rev. 03

**Report No.:** SH2010801_2
**Valid from:** 2020-09-18
**Valid until:** 2023-06-30

**Date,** 2020-09-18

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT