



Product Service

CERTIFICATE

No. Q1N 17 04 80430 008

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:



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, Ballon Tube
Production and Distribution of
Hip Joint System, Knee Joint System,
Instruments for Hip Joint System,
Instruments for Knee Joint System**

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: SH1710814

Valid from: 2017-07-05

Valid until: 2020-06-30

Date, 2017-07-05

Stefan Preiß



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