

Declaration of Conformity

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

European Representative: **Shanghai International Holding Corp. GmbH (Europe)**

Representative: **Eiffestraße 80, 20537 Hamburg, GERMANY**

Product name: **Lockable Intramedullary Nails**

Model Number: **JHD I~III, JJD I~VI, JCRD I, JGD I~VII, JGM I~VI**

GMDN Code: **56643(non-sterile), 56644(non-sterile), 56645(non-sterile), 47762(non-sterile),
38152(sterile), 38153(sterile), 33187(sterile), 48059(sterile), 46139**

Classification (MDD, Annex IX): **IIb, rule 8**

Conformity Assessment Route: **Annex II without chapter4**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC)

Notified Body: **TÜV SÜD Product Service GmbH Zertifizierstelle,**
Ridlerstraße 65, 80339 München, Germany

NB Identification number: **0123**

(EC) Certificate(s): **G1 17 04 80430 009**

Expire date of the Certificate: **2020-07-26**

Start of CE Marking: **2006-01-05**

Signature: 

Name: **Wally Wang**

Position: **Management Representative**

常州市康辉医疗器械有限公司
CHANGZHOU KANGHUI MEDICAL INNOVATION CO., LTD.

Place, Date of Issue: **Changzhou, 2017-07-20**