

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 **Shanghai International Holding Corp. GmbH (Europe)**

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

Product Category: **Lockable Intramedullary Nails**

Model Number: **JGD II, JJD V, JGD VII, JGD III, JGD VI, JGM II, JGM III, JGM V, JGD I, JGD IV,**
JGD V, JJD I, JJD III, JSDII, JSDIII, JSD IV, JSDVII, JSDVIII, JSDIX, JSDX

GMDN Code: **56643(non-sterile), 56645(non-sterile), 47762(non-sterile), 63875(non-sterile),**
38152(sterile), 33187(sterile), 48059(sterile),
46139(sterile) ,56642(Non-Sterile) ,46646(Sterile)

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. We are exclusively responsible for the DoC.

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

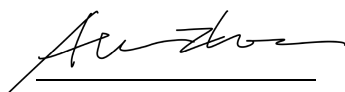
NB Identification number: **0123**

(EC) Certificate(s): **G1 080430 0010 Rev.01**

Expire date of the Certificate: **2024-05-26**

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

Signature: _____



Name: **Alina Zhou**

Position: **Senior Director of Quality and RA**

Place, Date of Issue: **Changzhou, 2020-04-28**