EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60124981 0001

Report No.: 15096167 001

Manufacturer:
Jiangsu Jinlu Group Medical Device
Co., Ltd.
Jinfeng Town
Zhangjiagang City
215625 Jiangsu
China

Products:
- Metal Bone Plates & Screw Systems
- Metallic Cannulated Bone Screws
- Metallic Interlocking Intramedullary Nails
  Spinal Fixation Devices
- External Fixation Devices with Needles
- Suture Wires

Expiry Date: 2022-06-30

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2017-12-11

Date: 2017-12-11

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.