EC Certificate

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

Registration No.: HD 60123225 0001

Report No.: 15096158 001

Manufacturer:
Suzhou Youbetter Medical Apparatus
Co., Ltd.
Chuangye Road, Jinfeng Town
Zhangjiagang
215625 Jiangsu
China

Products:
- Metal Bone Plates
- Metal Bone Screws
- Cannulated Bone Screws
- Metal Interlocking Intramedullary Nails
- Spinal Fixations
- Anterior Cervical Plates

Expiry Date: 2022-06-22

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: 2017-09-15

Date: 2017-09-15

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.