EC Certificate

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

Registration No.: HD 60147759 0001

Report No.: 15096158 007

Manufacturer:

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

Products:

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

Replaces Approval, Registration No.: DD 60123225 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2020-05-21

Date: 2020-05-21

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

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.

Digitally signed by Jighili Tatiana
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