

## **EC** Certificate

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

Registration No.: HD 60149781 0001

Report No.: 15096276 004

Manufacturer: Changzhou Medical Bioengineering

Co., Ltd.

No. 117, West Chenjiatou, Heping Village

Zhenglu Town, Tianning District

Changzhou City 213114 Jiangsu

P.R. China

Products: Disposable Infusion Pumps, Disposable Skin Staplers,

Circumcision Staplers For Single Use, Disposable

Laparoscopic Trocars

Replaces Approval, Registration No.: HD 60129796 0001

**Notified Body** 

Fuxiu Sheng

TÜVRheinland

**Expiry Date:** 2023-06-28

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: 2020-11-03

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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.