EC Certificate

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

TÜVRheinland®

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

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

Date: 2020-11-03

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.