EC Certificate

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

Registration No.: HD 60145044 0001

Report No.: 15047300 012

Manufacturer:
Jiangsu Ripe Medical Instruments
Technology Co., Ltd.
No. 12 of Group, Qianjing Cun
Jingcheng Town
Jingjiang City
214500 Jiangsu
China

Digitally signed by Rotari Vladimir
Date: 2022.03.18 08:35:14 EET
Reason: MoldSign Signature
Location: Moldova

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60121298 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: 2019-12-27

Date: 2019-12-27

Notified Body

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.