EC Certificate

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

Registration No.: HD 60126740 0001

Report No.: 15056254 008

Manufacturer:
Zhejiang Geyi Medical
Instrument Co., Ltd.
The 5th Floor, NO.4 Building
No.190 Chutian Road
Xixing Street, Binjiang Zone
Hangzhou
310051 Zhejiang
China

Digitally signed by Bunic Gheorghe
Date: 2021.12.31 11:21:21 EET
Reason: MoldSign Signature
Location: Moldova

Products: Disposable Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60110361 0001

Expiry Date: 2022-12-13

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: 2018-03-21

Date: 2018-03-21

Notified Body
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.