

EC Certificate



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

Registration No.: HD 2057271-1

Manufacturer: Zhejiang Geyi Medical Instrument
Co., Ltd.
No.1,2 Factory, No.5, Hutang Road,
Xiaya Town, Jiande City,
311606 Zhejiang
P.R. China

Products: Disposable Cutting Surgical Staplers, Disposable Surgical Staplers,
Disposable Hemorrhoidal Surgical Staplers, Disposable Trocars,
Disposable Suction Irrigation Sets, Disposable Endoscopic Retrieval Bags,
Disposable Curved Cutting Staplers, Disposable Circumcision Staplers,
Disposable Veress Insufflation Needles

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.

Report No.: 15056254 014

Effective date: 2021-05-17

Expiry date: 2022-12-13

Issue date: 2021-05-17



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2057271-1

Organization: Zhejiang Geyi Medical Instrument
Co., Ltd.
No.1,2 Factory, No.5, Hutang Road,
Xiaya Town, Jiande City,
311606 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable
Cutting Surgical Staplers, Disposable Surgical Staplers, Disposable
Hemorrhoidal Surgical Staplers, Disposable Trocars, Disposable Suction
Irrigation Sets, Disposable Endoscopic Retrieval Bags, Disposable Curved
Cutting Staplers, Disposable Circumcision Staplers, Disposable Veress
Insufflation Needles

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 15056254 014
Effective date: 2021-04-14
Expiry date: 2023-12-13
Issue date: 2021-04-14



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany