EC Certificate

TÜVRheinland

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

Registration No.: HD 60140258 0001

Report No.: 17054655 002

Manufacturer:
Shenzhen InnoSurg Medical Technology
Co., Ltd.
3/F, Building 7,
No.14 Zhongxing Road, Kengzi, Pingshan District
518122 Shenzhen, Guangdong
China

Products:
Disposable Laparoscopic Trocars,
Disposable Veress Needles,
Disposable Laparoscopic Specimen Retrieval Bags,
Disposable Laparoscopic Trocar Kits

Expiry Date: 2024-05-27

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: 2019-12-02

Date: 2019-12-02

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
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.

Digitally signed by Rotari Vladimir
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