EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

Registration No.: DD 60147761 0001

Report No.: 15050482 012

Manufacturer:
Sihong Surgitrac Co., Ltd.
No. 2, Xihu Road
Sihong Industrial Park
Jiangsu 223900
P.R. China

Products:
Disposable Ophthalmic Surgical Instruments

(see attachment for products included)

Replaces Approval, Registration No.: DD 60123069 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-06-28

Date: 2020-06-28

Notified Body

Fuxiu Sheng

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

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.