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TÜVRheinland®

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

Registration No.: DD 60141341 0001

Report No.: 15096370 002

Manufacturer:
Yingtai Suzhou Medical Technology
Co., Ltd.
No.390, Yongjin Road, Miaoqiao Street
Tangqiao Town
Zhangjiagang
215615 Jiangsu
P.R. China

Products:
Disposable Circumcision Staplers, Disposable Laparoscopic Trocars
Aspects of manufacture concerned with securing and maintaining sterile conditions: Surgical Gowns, Sterile Surgical Procedure Kits

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: 2020-05-09

Date: 2020-05-09

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH, TÜVRheinland®, III, 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.