SHENGGUANG MEDICAL INSTRUMENT CO.,LTD

ADD.EAST OF LONGSHAN ROAD, JIAXIAN, PINGDINGSHAN, HENAN, CHINA WWW.SHENGGUANGMEDICAL.COM;

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

TÜVRheinland

Registration No.: DD 60127088 0001

Report No.:

15044773 009

Manufacturer:

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60114594 0001

Expiry Date:

2021-10-22

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 III and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date:

2018-07-06

Date:

2018-07-06

Notified Body

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.

SHENGGUANG MEDICAL INSTRUMENT CO.,LTD

ADD.EAST OF LONGSHAN ROAD, JIAXIAN, PINGDINGSHAN, HENAN, CHINA WWW.SHENGGUANGMEDICAL.COM;



Doc. 2/2, Rev. 0 TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Report No .:

Registration No.: DD 60127088 0001 15044773 009

Manufacturer:



Aspects of manufacture concerned with securing and maintaining sterile conditions: Disposable Drainage Bags, Disposable Medical Pads, Medical Caps, Surgical Masks, Disposable Suction Catheters, Disposable Spatula, Disposable Vaginal Dilators, Wound Plasters, Drainage Tubes for Single Use, Sterile Medical Cotton Balls, Sterile Medical Sheets, Sterile Cotton Swabs, Examination Gloves, Disposable Dressing Kits, Medical Absorbent Gauze Pieces, Medical Absorbent Gauze Pads, Disposable Medical Films, Positive Pressure Needle-Free Infusion Connectors, Medical Use Cotton Rolls, Medical Gauze Bandages, Medical Elastic Bandages, Oropharyngeal Airways, Disposable Sterile Dispensing Syringes, Disposable Delivery Kits, Medical Masks, Protectors for Transfusion Joint, Disposable Oral Irrigation Tubes

Date: 2018-07-06

Notified B X. Rei