

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

Registration No.: DD 60137412 0001

Report No.: 15067095 009

Manufacturer: Jiangsu Weikang Jiejing Medical
Apparatus Co., Ltd.
18 # Wenzhou Rd.
Economical Development District
Shuyang
223600 Jiangsu
China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: DD 60093382 0001

Expiry Date: 2024-04-16

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: 2019-04-26

Date: 2019-04-26

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60137412 0001
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18 # Wenzhou Rd.
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Products:

Disposable Venturi Masks, Disposable Nasal
Oxygen Cannulae, Disposable Suction Connecting Tubes,
Disposable Tracheal Tubes (Standard & Reinforced),
Disposable Oxygen Masks, Non-Rebreathing Masks, Aerosol
Masks, Disposable Feeding Tubes, Disposable Rectal Tubes,
Disposable Urinary Catheters (Standard & Hydrogel Coated),
Disposable Mucous Extractors, Yankauer, Nebulizer,
Laryngeal Mask Airways, Disposable Drainage Tubes,
Disposable Tracheostomy Masks, Disposable Suction
Catheters, Disposable Stomach Tubes, Closed Suction
Catheters, Anesthesia Face Masks;

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

Disposable Irrigating Syringes, Disposable Syringe
Cleaners, Disposable Nasoscopes, Disposable Closed Drainage
Bottles, Feeding Bags, Oral Pharyngeal Airways, Surgical
Razors, Disposable Drainage Bags, Disposable Incubating
Stylet, Finger Tip Connectors, Suction Liner

Date: 2019-04-26

Notified Body

Fuxiu Sheng

