

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

Registration No.: DD 60151185 0001

Report No.: 15049271 019

Manufacturer: Hangzhou Shanyou Medical Equipment

Co., Ltd.

No. 138, Louta Development Zone

Guancun Village, Louta Town

Xiaoshan District

Hangzhou

311266 Zhejiang

P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60147797 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:

2020-08-07

Date:

2020-08-07

Notified Body

TÖVRheinland

Fuxiu Sheng

Tövrheinland

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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.



Doc. 1/1 Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

DD 60151185 0001

Report No.:

15049271 019

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Co., Ltd.
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Products:

- Endotracheal Tubes
- Laryngeal Mask Airways
- Laryngoscope Blades
- Face Masks

(Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask)

- Suction Catheters
- Nasal Oxygen Cannulas
- Disposable Breathing Circuits
- Yankauer Suction Sets
- Anesthesia Masks
- Filters/HMEF
- Catheter Mounts
- Nasogastric Tubes

Aspects of manufacture concerned with securing and maintaining sterile conditions only:

- Endotracheal Tube Holders
- Artery Compression Tourniquets
- Intubating Stylets
- Guedel Airways
- Medical Face Masks

Date: 2020-08-07

Fuxiu Sheng

Notified Body

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