

ISO Certification



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Hangzhou Shanyou Medical Equipment
Co., Ltd.**

No. [REDACTED]
**Guancun Village, Louta Town
Xiaoshan District
Hangzhou
311266 Zhejiang
China**

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-07-19
Certificate Registration No.: SX 60129360 0001
An audit was performed. Report No.: 15049271 010
This Certificate is valid until: 2020-04-17

Certification Body



Date 2018-07-19



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
 Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: SX 60129360 0001
Report No.: 15049271 010

Organization:

Hangzhou Shanyou Medical Equipment Co., Ltd.
 No. [REDACTED]
 Guancun Village, Louta Town
 Xiaoshan District
 Hangzhou
 311266 Zhejiang
 China

Scope:

Design and Development, Manufacture and Distribution of Disposable Breathing Circuits;
 Manufacture and Distribution of Endotracheal Tubes, Laryngeal Mask Airways, Laryngoscope Blades, Face Masks (Oxygen Mask, Non-rebreathing Mask, Nebulizer Mask), Suction Catheters, Nasal Oxygen Cannulas, Endotracheal Tube Holders, Artery Compression Tourniquets, Intubating Stylets, Guedel Airways, Yankauer Suction Sets, Anesthesia Masks, Filters/HMEF, Catheter Mounts, Nasogastric Tubes

Certification Body



Date: 2018-07-19

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CE certification



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

Registration No.: DD 60129357 0001

Report No.: 15049271 010

Manufacturer: Hangzhou Shanyou Medical Equipment Co., Ltd.

[Redacted]
 [Redacted]
 Xiaoshan District
 Hangzhou
 311266 Zhejiang
 China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60118922 0001

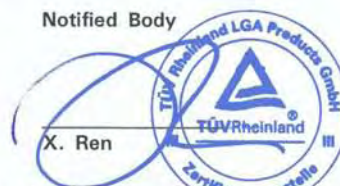
Expiry Date: 2022-04-17

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: 2018-07-19

Date: 2018-07-19

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.

CE certification



Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
 Certificate**

Registration No.: DD 60129357 0001
Report No.: 15049271 010

Manufacturer: Hangzhou Shanyou Medical Equipment Co., Ltd.

[Redacted]
 Xiaoshan District
 Hangzhou
 311266 Zhejiang
 China

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

Date: 2018-07-19

Notified Body

