

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

**Registration No.:** DD 60112728 0001

**Report No.:** 15095315 001

**Manufacturer:** Changzhou ZhongYou Medical  
Device Co., Ltd.  
Wugang, Zhenglu Town  
Changzhou  
213115 Jiangsu  
China

**Products:** Medical Devices  
(see attachment for products included)  
Replaces Approval, Registration No.: DD 60040100 0001

**Expiry Date:** 2021-07-28

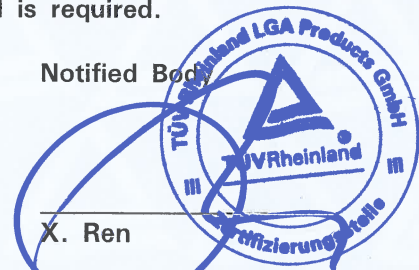
The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned 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:** 2016-08-08

**Date:** 2016-08-08

Notified Body

X. Ren



**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 60112728 0001  
**Report No.:** 15095315 001

**Manufacturer:** Changzhou ZhongYou Medical  
Device Co., Ltd.  
Wugang, Zhenglu Town  
Changzhou  
213115 Jiangsu  
China

**Products:**

- Suction Catheters
- Stomach Tubes
- Feeding Tubes
- Mucus Extractors
- Urinary Catheters (Nelaton Catheters, Tiemann Catheters)
- Oxygen Masks
- Nebulizer Masks

For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Nasal Oxygen Cannulae
- Disposable Urine Drainage Bags
- Cervical Scrapers
- Medical Brushes
- Rectal Catheters
- Suction Connecting Tubes with Yankauer

**Date:** 2016-08-08

**Notified Body**

**X. Ren**

