

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60118775 0001

**Report No.:** 17054840 003

**Manufacturer:** Shunmei Medical  
Co., Ltd.  
R401 of building B, No.8 of  
1st Jinglong Road, Baolong  
Industrial Zone, LongGang District,  
518116 Shenzhen, Guangdong  
China

**Products:** Medical Devices  
  
(see attachment for products and additional sites included)  
  
Replaces Approval, Registration No.: HD 60107860 0001

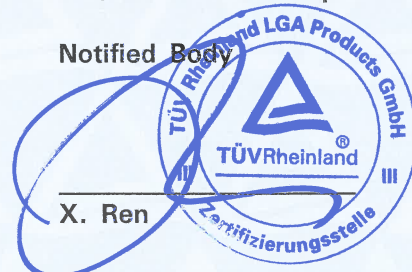
**Expiry Date:** 2021-03-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-08-29

**Date:** 2017-08-29

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**

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

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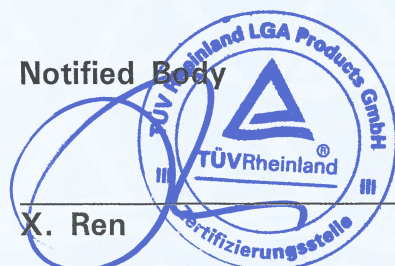
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**Products:**

- Disposable Pressure Transducers
- Hemodialysis Catheter Kits
- Connecting Tubing
- Introducer Sets
- Guide Wires
- Hemostasis Valve Set
- Ureteral Stent Set
- Introducer Needle
- Angiographic Syringe
- Closed Suction Kit
- Drainage Catheter
- Tracheostomy Tube
- Percutaneous Nephrostomy Sets
- Cervical Ripening Balloon
- Postpartum Balloon with Rapid Instillation Components

**Date:** 2017-08-29

**Notified Body**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringe
- Manifold Kit
- Angio-closure Pad
- TR-Closure Band
- Needle-free Connector

Sites included:

Floor1-floor3 of building C, No.8 of 1st Jinlong Road,  
Baolong Industrial Zone, LongGang District,  
518116 Shenzhen, Guangdong, China

Huizhou branch of Shunmei Medical Co., Ltd  
Yifa industrial zone, Dushi village, Pingtan town,  
HuiYang District, HuiZhou City, China

**Date: 2017-08-29**

