

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

Registration No.: HD 60147577 0001

Report No.: 17054840 009

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

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60136963 0001

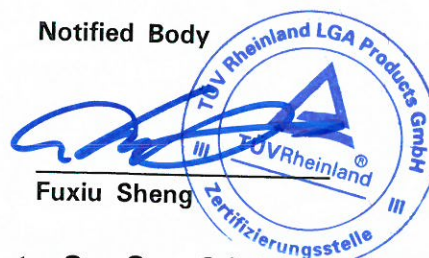
Expiry Date: 2024-05-26

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: 2020-08-09

Date: 2020-08-09

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

Doc. 1/2 Rev. 0

**Attachment to
Certificate**

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Products:

- Disposable Pressure Transducers
- Hemodialysis Catheter Kits
- Connecting Tubings
- Introducer Sets
- Guide Wires
- Hemostasis Valve Sets
- Ureteral Stent Sets
- Introducer Needles
- Angiographic Syringes
- Closed Suction Kits
- Drainage Catheters
- Tracheostomy Tubes
- Percutaneous Nephrostomy Sets
- Cervical Ripening Balloons
- Postpartum Balloons with Rapid Instillation Components

Date: 2020-08-09

Notified Body


Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

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Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringes
- Manifold Kits
- Angio-closure Pads
- TR-Closure Bands
- Needle-free Connectors

Site included:

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

Date: 2020-08-09

Notified Body



Fuxiu Sheng

