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.

Notified Body

TÜV Rheinland LGA Products GmbH – TÜVRheinland – Zertifizierungsstelle – II – III

X. Ren

Effective Date: 2017-08-29

Date: 2017-08-29

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
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Report No.: 17054840 003

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Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
China

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

Notified Body

Date: 2017-08-29

X. Ren

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60118775 0001
Report No.: 17054840 003

Manufacturer:
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Co., Ltd.
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Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
China

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-08-29

X. Ren