

**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

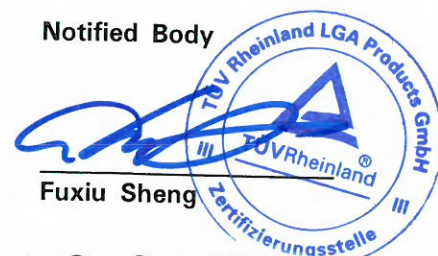
**Expiry Date:** 2024-05-26

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**

**Attachment to  
Certificate**

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**Manufacturer:** Shunmei Medical  
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R401 of building B, No.8 of  
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518116 Shenzhen, Guangdong  
P.R. China

**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**

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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**





**Shunmei**<sup>®</sup>

Shunmei Medical Co.,LTD

Address: R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Long Gang District, 518116, Shenzhen, Guangdong China.

Tel: +86 755-89217210

Fax: +86 755-89718539

Email: nora1@shunmed.com web: www.shunmed.com

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## EC Declaration of Conformity

*Design & Manufacturer:*

**Shunmei Medical Co., Ltd.**

Add: R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, LongGang District, Shenzhen city, Guangdong, 518116, China.

Tel: +00867523306929  
Email: Jane@shunmed.com

*whose single Authorized Representative:*

**Lotus NL B.V.**

Add: Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

Tel: +31645171879(English)  
Tel: +3162669008(Dutch)  
Email: peter@lotusul.com

We, the manufacturer, herewith declare that the products  
**Balloon Inflation Devices**  
meet the provisions of Directive 93/42/EEC which apply to them.

**GMDN code** : 17541, 17541 - Inflator, angioplasty balloon - Description : A dedicated hand-held device, e.g. a syringe or small pump, with a pressure gauge that is used for inflating the balloon of an angioplasty balloon catheter when this is in situ. The pressure applied can be considerable during a coronary artery dilatation procedure, a procedure known as a percutaneous transluminal coronary angioplasty.

**Product model** : see Annex 1.

The medical device has been assigned to Class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

**C** **€0197**

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

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

Certificate No.: HD 60118775 0001

Issue date: 29.08.2017

Expiry date: 09.03.2021

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all



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products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **Shunmei Medical Co., Ltd.**

Address: R401 of building B, No.8 of 1st Jinglong Road, Baolong Industrial Zone, LongGang District, Shenzhen city, Guangdong, 518116, China

Shenzhen, 2019.06.15

**Place, date**

General manager

**Legally binding signature, Function**

**Annex 1 Product models of Balloon Inflation Devices**

<b>Balloon inflation devices</b>	
<b>Normal type</b>	
Code	Description
617101	BID1(20ml,30atm)
617102	BID2(25ml,30atm)
617103	BID3(30ml,30atm)
617104	BID4(20ml,30atm) (push pull Y connector without extension line+insertion tool+torquer)
617105	BID5(20ml,30atm) (push pull Y connector with extension line+insertion tool+torquer)
617117	BID17(20ml,30atm) (screw Y connector without extension line+insertion tool+torquer)
617118	BID18(20ml,30atm) (screw Y connector with extension line+insertion tool+torquer)
617106	BID6(30ml,30atm) (screw Y connector without extension line+insertion tool+torquer)
617107	BID7(30ml,30atm) (push-pull type with extension line+insertion tool+torquer)
617119	BID19(30ml,30atm) (screw Y connector with extension line+insertion tool+torquer)
617120	BID20(30ml,30atm) (push pull Y connector without extension line+insertion tool+torquer)
<b>Gun type</b>	
617108	BID8(20ml,30atm)
617109	BID9(30ml,30atm)
617110	BID10(20ml,40atm)
617111	BID11(25ml,40atm)
617112	BID12 (30ml,40atm)
617113	BID13(20ml,30atm) (push pull Y connector with extension line+insertion tool+torquer)

Shunmei Medical Co.,LTD

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617114	BID14(20ml,30atm) (push pull Y connector without extension line+insertion tool+torquer)
617115	BID15(20ml,30atm) (screw Y connector without extension line+insertion tool+torquer)
617116	BID16(20ml,30atm) (screw Y connector with extension line+inestion tool+torquer)
617122	BID22(20ml,40atm) (push pull Y connector without extension line+insertion tool+torquer)
617123	BID23(20ml,40atm) (push pull Y connector with extension line+insertion tool+torquer)
617124	BID24(20ml,40atm) (screw Y connector with extension line+inestion tool+torquer)
617125	BID25(20ml,40atm) (screw Y connector without extension line+inestion tool+torquer)

<b>Semi-gun type</b>	
Code	Description
617126	BID26(20ml,30atm)
617127	BID27(20ml,30atm) (Click Y connector with extension line+insertion tool+torquer)
617128	BID28(20ml,30atm) (Click Y connector without extension line+insertion tool+torquer)
617129	BID29(20ml,30atm) (push pull Y connector with extension line+insertion tool+torquer)
617130	BID30(20ml,30atm) (push pull Y connector without extension line+insertion tool+torquer)

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

**Design and Development, Manufacture  
and Distribution of Medical Devices**  
(see attachment for products and additional sites 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: 2019-12-13  
Certificate Registration No.: SX 60136964 0001  
An audit was performed. Report No.: 17054840 005  
This Certificate is valid until: 2022-03-09

Certification Body



Date 2019-12-13



Herbert Zhong

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

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

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**Report No.:** 17054840 005

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**Scope:**

**Products:**

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- Cervical Ripening Balloons
- Postpartum Balloons with Rapid Instillation Components
- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringes

**Certification Body**



**Date:** 2019-12-13

**Herbert Zhong**



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**Scope:**

**Products:**  
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- Angio-closure Pads  
- TR-Closure Bands  
- Needle-free Connectors

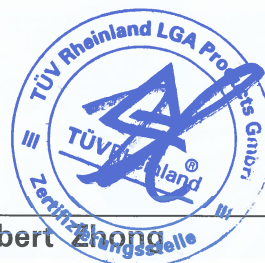
**Sites included:**  
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Industrial Zone, LongGang District, 518116 Shenzhen,  
Guangdong, China

Manufacture of the mentioned products

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

Design and Development, Manufacture and Distribution of  
the mentioned products

**Certification Body**



**Date: 2019-12-13**

**Herbert Zhong**