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

Fuxiu Sheng

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.

Digitally signed by Iarovoi Petru
Date: 2021.09.08 17:30:44 EEST
Reason: MoldSign Signature
Location: Moldova

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/2 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- 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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-08-09

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilication and application requires prior approval.

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Fuxiu Sheng

Date: 2020-08-09

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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

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

CE 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

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

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***

TuzhenJin *,General manager* — ***Legally binding signature, Function***

Annex 1 Product models of Balloon Inflation Devices

Balloon inflation devices	
Normal type	
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)
Gun type	
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
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

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)

Semi-gun type	
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)

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-12-13

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60136964 0001
Report No.: 17054840 005

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

Scope:

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
- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringes

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Date: 2019-12-13

Herbert Zhong

10/020 d 04.08 © TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60136964 0001
Report No.: 17054840 005

Organization:

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

Scope:

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

Sites included:
Shunmei Medical Co., Ltd.
R401 of building B, No.8 of 1st Jinglong Road, Baolong 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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Date: 2019-12-13

Herbert Zhong

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.