EC Declaration of Conformity

Design & Manufacturer:

Shunmei Medical Co., Ltd.

Add: R401 of building B, No.8 of 1st Jinglong Road, Baolong Industrial Zone, LongGang District, Shenzhen, 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 as following:

No.	Product name	Classification
1	Hemodialysis Catheter Kits	Class IIa
2	Disposable Pressure Transducers	Class IIa
3	Introducer Sets	Class IIa
4	Connecting Tubings	Class IIa
5	Hemostasis Valve Set	Class IIa
6	Guide Wires	Class IIa
7	Ureteral Stent Sets	Class IIa
8	Stopcocks	Class IS
9	Balloon Inflation Devices	Class IS
10	Dose Control Syringes	Class IS
11	Manifolds	Class IS
12	Manifold Kits	Class IS
13	Angiographic Syringes	Class IIa
14	Introducer Needles	Class IIa
15	Drainage Catheters	Class IIa
16	Closed Suction Kits	Class IIa
17	Angio-closure Pads	Class IS
18	TR-Closure Bands	Class IS
19	Tracheostomy Tubes	Class IIa
20	Percutaneous Nephrostomy Sets	Class IIa
21	Cervical Ripening Balloons	Class IIa
22	Postpartum Balloon with Rapid Instillation Components	Class IIa
23	Needle-free Connectors	Class IS

meet the provisions of Directive 93/42/EEC which apply to them.

The all medical devices in above table have been assigned to Classification according to Annex IX of the Directive 93/42/EEC. They bears the mark

CE 0197

The products concerned have 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 60147577 0001
Issue date: 2020-08-09
Expiry date: 2024-05-26

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 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, 2020.08.18
Place, date

Tuzhen Jin ,General manager
Legally binding signature, Function