

## EC Declaration of Conformity

Manufacturer:

Name: Zibo Eastmed Healthcare  
Products Co., Ltd

Add: No.99 Lutai Road, Gaoxin District  
Zibo, 255086 Shandong, China

whose single Authorized Representative  
Name: SUNGO Certification Company  
Limited

Add: RM101, MAPLE HOUSE,  
118 HIGH STREET, PURLEY,  
LONDON, ENGLAND

We, the manufacturer, herewith declare that the products

**Blood collection needle set**

meet the provisions of MDD 93/42/EEC Amended by 2007/47/EC which apply to  
them

The medical device has been assigned to class is according to (MDD Annex V. rule X):  
IIa. It bears the mark

**CE 0197**

The product concerned has been manufactured under a quality management system  
according to MDD 93/42/EEC Amended by 2007/47/EC.

Compliance of the designated product with the MDD 93/42/EEC Amended by  
2007/47/EC has been assessed and certified by the Notified Body

**TüV Rheinland LGA Products GmbH,**

**Tillystrabe 2 – 90431 Nürnberg**

Certificate No: HD 60111852 0001

Issue date: 05.09.2016

Expiry date: 16.08.2021

following the procedure relating to the EC Declaration of Conformity set out in MDD  
93/42/EEC Amended by 2007/47/EC.

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

**Company: Zibo Eastmed Healthcare Products Co., Ltd**

**Address: No.99 Lutai Road, Gaoxin District, Zibo City 25508,  
Shandong, China**

2017. 10. 25

Place, date

John W

Legally binding signature, Functio

*For and on behalf of*  
ZIBO EASTMED HEALTHCARE PRODUCTS CO., LIMITED

.....  
*Authorized Signature(s)*

# EC Declaration of Conformity

*Manufacturer:*

Name: Xiantao Xingrong Protective Products Co., Ltd.  
Add: No.46, East of Pengchang Road, Xiantao, Hubei  
433018, China  
Tel: 0728-2613199 Fax: 0728-2611166

*whose single Authorized Representative:*

**Company Name: Renault-Petersen Limited**  
**Company Address: 5 Bankside, Han borough**  
**Business Park, Witney OX29 8LJ**  
**UK**  
**Tel: +44 1993 882779, Fax: +44 1993 880110**

We, the manufacturer, herewith declare that the products

**Plastic Shoe Cover**

(including system components and accessories)

UMDNS-Code: 13574

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

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 manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC aspects of manufacture concerned with securing and maintaining sterile conditions has been assured via assessment of the quality management system by the Notified Body

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

Certificate No.: DD 60104282 0001

Issue date: 2015-10-16

Expiry date: 2020-10-15

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

**Company: Xiantao Xingrong Protective Products Co., Ltd**  
**Address: No.46, East of Pengchang Road, Xiantao, Hubei 433018 China**

2017-09-20  
Place, date



Li Xiang  
Legally binding signature, Function