

**EC DECLARATION OF CONFORMITY**

Document number / version : STP-30018

Name and address of the manufacturer: **Jiaxing Tianhe Pharmaceutical Co., Ltd.**  
**Zhongfa Foreign Trade Industrial Zone, Fengqiao Town, Nanhu**  
**District, Jiaxing City, Zhejiang Province 314008, China**

whose single Authorized Representative: **OBELIS S.A**  
**Add: Bd.Général Wahls, 53 1030 Brussels, Belgium**

We declare under our sole responsibility that

the medical device: **Disposable Plastic Blood Bags (Top&Bottom)**  
**GMDN-Code/Preferred Terms: 44037; Blood donor set,**  
**Triple-pack**

**Type:Various**

of class: **IIb**

According to the rule 18 from the Annex IX of the Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure: / **Directive 93/42/EEC Annex II ,**

Registration No.: **HD 60147247 0001**

Notified Body: /

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2**  
**90431 Nürnberg**  
**Deutschland**  
**CE 0197**

Jiaxing 2021/5/6  
Place, date

[Signature] Manager Representative  
Name and function

## EC DECLARATION OF CONFORMITY

Document number / version : STP-30027

Name and address of the manufacturer: **Jiaying Tianhe Pharmaceutical Co., Ltd.**  
**Zhongfa Foreign Trade Industrial Zone, Fengqiao Town, Nanhu**  
**District, Jiaying City, Zhejiang Province 314008, China**

whose single Authorized Representative: **OBELIS S.A**  
**Add: Bd.Général Wakis, 53 1030 Brussels, Belgium**

We declare under our sole responsibility that

the medical device: **Transfer bag**  
**GMDN-Code/Preferred Terms: 44033; Blood donor set,**  
**Single-pack**

**Type:Various**

of class: **IIb**

According to the rule 18 from the Annex IX of the Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure: / **Directive 93/42/EEC Annex II,**

Registration No.: **HD 60147247 0001**

Notified Body: /

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2**  
**90431 Nürnberg**  
**Deutschland**  
**CE 0197**

Jiaying, 2021/5/6  
Place, date

  
Manager Representative  
Name and function

**EC DECLARATION OF CONFORMITY**

Document number / version : STP-30022

Name and address of the manufacturer: **Jiaying Tianhe Pharmaceutical Co., Ltd.  
Zhongfa Foreign Trade Industrial Zone, Fengqiao Town, Nanhu  
District, Jiaxing City, Zhejiang Province 314008, China**

whose single Authorized Representative: **OBELIS S.A  
Add: Bd.Général Wahls, 53 1030 Brussels, Belgium**

We declare under our sole responsibility that

the medical device: **Disposable Plastic Blood Bags with Leukocyte-reduced Filter  
GMDN-Code/Preferred Terms: 44037; Blood donor set,  
Tripte-pack**

**Type:Various**

of class: **IIb**

According to the rule 18 from the Annex IX of the Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Conformity assessment procedure: / **Directive 93/42/EEC Annex II,**

Registration No.: **HD 60147247 0001**

Notified Body: /

**TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg  
Deutschland  
CE 0197**

**Jiaying, 2021/5/6**  
Place, date

  
**Manager Representative**  
Name and function