

EC DECLARATION OF CONFORMITY

Document number / version : STP-30018

Name and address of the manufacturer: **Jlaxing 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 Wahis, 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


Manager Representative
Name and function

EC DECLARATION OF CONFORMITY

Document number / version : STP-30027

Name and address of the manufacturer: **Jlaxing 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 Wahis, 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
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90431 Nürnberg
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Jiaxing, 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: **Jlaxing 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 Wahis, 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,
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
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Manager Representative
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