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 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

Digitally signed by Bolea Petru
Date: 2021.10.18 20:03:28 EEST
Reason: MoldSign Signature
Location: Moldova

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:	**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 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** **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-30022**

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 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** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Jiaxing, 2021/5/6
Place, date

Manager Representative
Name and function