# 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: 2022.11.27 17:41:02 EET
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**

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|---|---|
| Name and address of the manufacturer: | **Jiaxing Tianhe Pharmaceutical Co., Ltd.**<br>**Zhongfa Foreign Trade Industrial Zone, Fengqiao Town, Nanhu District, Jiaxing City, Zhejiang Province 314008, China** |
| whose single Authorized Representative: | **OBELIS S.A**<br>**Add: Bd.Général Wahis, 53 1030 Brussels, Belgium** |

We declare under our sole responsibility that

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

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|---|---|
| Conformity assessment procedure: / | **Directive 93/42/EEC Annex II,** |
| Registration No.: | **HD 60147247 0001** |
| Notified Body: / | **TÜV Rheinland LGA Products GmbH**<br>**Tillystraße 2**<br>**90431 Nürnberg**<br>**Deutschland**<br>**CE 0197** |

Jiaxing, 2021/5/6
Place, date

Manager Representative
Name and function

# EC DECLARATION OF CONFORMITY

Document number / version : **STP-30022**

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|---|---|
| Name and address of the manufacturer: | **Jiaxing Tianhe Pharmaceutical Co., Ltd.**<br>**Zhongfa Foreign Trade Industrial Zone, Fengqiao Town, Nanhu District, Jiaxing City, Zhejiang Province 314008, China** |
| whose single Authorized Representative: | **OBELIS S.A**<br>**Add: Bd.Général Wahis, 53 1030 Brussels, Belgium** |

We declare under our sole responsibility that

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|---|---|
| the medical device: | **Disposable Plastic Blood Bags with Leukocyte-reduced Filter**<br><br>**GMDN-Code/Preferred Terms: 44037; Blood donor set, Triple-pack**<br><br>**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. /

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|---|---|
| Conformity assessment procedure: / | **Directive 93/42/EEC Annex II,** |
| Registration No.: | **HD 60147247 0001** |
| Notified Body: / | **TÜV Rheinland LGA Products GmbH**<br>**Tillystraße 2**<br>**90431 Nürnberg**<br>**Deutschland**<br>**CE 0197** |

Jiaxing, 2021/5/6
Place, date

Manager Representative
Name and function