

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: **Disposable Plastic Blood Bags**

GMDN-Code/Preferred Terms: 44033; Blood donor set, single-pack
GMDN-Code/Preferred Terms: 44034; Blood donor set, double-pack
GMDN-Code/Preferred Terms: 44037; Blood donor set, triple-pack
GMDN-Code/Preferred Terms: 46347; Blood donor set, quad-pack
GMDN-Code/Preferred Terms: 47747; Blood donor set, quint-pack
GMDN-Code/Preferred Terms: 47885; Blood donor set, many-pack
Type: Various Single Transfer Bags and Platelet Pooling Systems

of class: **II b**

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

Jiaxing, 2022-06-01
Place, date



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