

EC DECLARATION OF CONFORMITY

Document number / version : **SMP/QA-902-A5., C/4**

Name and address of the manufacturer: Suzhou Laishi Transfusion Equipment Co., Ltd.

Changsheng Road, Tongli Town, 215217 ,Wujiang City,
Jiangsu Province China

We declare under our sole responsibility that

The medical device: Disposable Plastic Blood Bag
Model: see attachment

Classification: IIb

According to annex IX of directive 93/42/EEC / and following harmonized standards

The product meets the provisions of the directive 93/42/EEC which apply to this declaration relates is in conformity with the following applied harmonized standard:

EN ISO13485: 2016:Quality management system of medical devices For regulatory requirements
EN ISO14971: 2012 :Medical devices, risk management, application of risk management to medical devices
MDD93/42/EEC、 MDD2007/47/EEC European Union' s Medical Devices Directive
EN ISO10993.1: 2018 Biological evaluation of medical devices Part 1: guidance on selection of test
EN 1041:2008 :Information supplied by the manufacturer of medical devices(terms, symbols, information)
EN 980: 2008: Graphical symbols for use in the labeling of medical devices

Conformity assessment procedure: /

**Directive 93/42/EEC Annex II , excluding Section 4 Full
Quality Assurance System**

Registration No.:

HD 60095681 0001

Notified Body: /

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

TONGLI date 2019.8.01

Place, date

Shenjian Function:QMR

Name and function

Shenjian
2019-8-1

Product(s)	Model	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only
Disposable Plastic Blood Bags	AC4.0 (200、250、300、350、400、450、500)	Blood donor set , single-pack	44033
	AC4.0 (200、250、300、350、400、450、500)	blood donor set, double-pack	44034
	AC4.0 (200、250、300、350、400、450、500)	blood donor set, triple-pack	44037
	AC4.0 (200、250、300、350、400、450、500)	blood donor set, quad-pack	46347
	ACD-A (200、250、300、350、400、450、500)	blood donor set ,single-pack	44033
	ACD-A (200、250、300、350、400、450、500)	blood donor set , double-pack	44034
	ACD-A (200、250、300、350、400、450、500)	blood donor set, triple-pack	44037
	ACD-A (200、250、300、350、400、450、500)	blood donor set, quad-pack	46347
	Disposable Plastic Blood Bags types: S(100、150、200、250、300、350、400、450、500) Anticoagulants: CPDA or CPD or ACD-B	blood donor set , single-pack	44033
	Disposable Plastic Blood Bags types: D(100、150、200、250、300、350、400、450、500) Anticoagulants: CPDA or CPD or ACD-B	blood donor set , double-pack	44034
	Disposable Plastic Blood Bags types: T(200、250、300、350、400、450、500) Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, triple-pack	44037

Disposable Plastic Blood Bags	Disposable Plastic Blood Bags types: Q(200、250、300、350、400、450、500) Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quad-pack	46347
	Disposable Plastic Blood Bags types: Qu(200、250、300、350、400、450、500) Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quin-pack	47747
	Disposable Plastic Blood Bags types: Mu(200、250、300、350、400、450、500) Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, many pack	47885
	Disposable Plastic Blood Bags(Top&Bottom) types: T(200、250、300、350、400、450、500)TB Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, triple-pack	44037
	Disposable Plastic Blood Bags(Top&Bottom) types: Q(200、250、300、350、400、450、500)TB Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quad-pack	46347
	Disposable Plastic Blood Bags(Top&Bottom) types: Qu(200、250、300、350、400、450、500)TB Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quin-pack	47747
	Disposable Plastic Blood Bags(Top&Bottom) types: Qu(200、250、300、350、400、450、500)TB Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quin-pack	47747

Disposable Plastic Blood Bags	Disposable Plastic Blood Bags(Top&Bottom) types: Mu(200、250、300、350、400、450、500)TB Anticoagulants or(and) Additive Solution: CPDA or CPD or ACD-B or CPD(CPDA)-SAGM(MAP) or ACD-B -SAGM(MAP)	blood donor set, many pack	47885
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter types: SL(100、150、200、250、300、350、400、450、500)	blood donor set ,single-pack	44033
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter types: DL(100、150、200、250、300、350、400、450、500)	blood donor set ,double-pack	44034
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter types: TL(200、250、300、350、400、450、500) Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B -SAGM(MAP)	blood donor set, triple-pack	44037
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter types: QL(200、250、300、350、400、450、500) Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B -SAGM(MAP)	blood donor set, quad-pack	46347
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter types: QuL(200、250、300、350、400、450、500) Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B -SAGM(MAP)	blood donor set, quin-pack	47747
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter(Top&Bottom) types: MuL (200、250、300、350、400、450、500)TB Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B -SAGM(MAP)	blood donor set, many pack	47885

Disposable Plastic Blood Bags	Disposable Plastic Blood Bags with Leukocyte-reduced Filter(Top&Bottom) types: TL(200、250、300、350、400、450、500)TB Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, triple-pack	44037
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter(Top&Bottom) types: QL(200、250、300、350、400、450、500)TB Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quad-pack	46347
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter(Top&Bottom) types: QuL(200、250、300、350、400、450、500)TB Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, quin-pack	47747
	Disposable Plastic Blood Bags with Leukocyte-reduced Filter(Top&Bottom) types: MuL (200、250、300、350、400、450、500)TB Anticoagulants and Additive Solution: CPD(CPDA)-SAGM(MAP) or ACD-B-SAGM(MAP)	blood donor set, many pack	47885