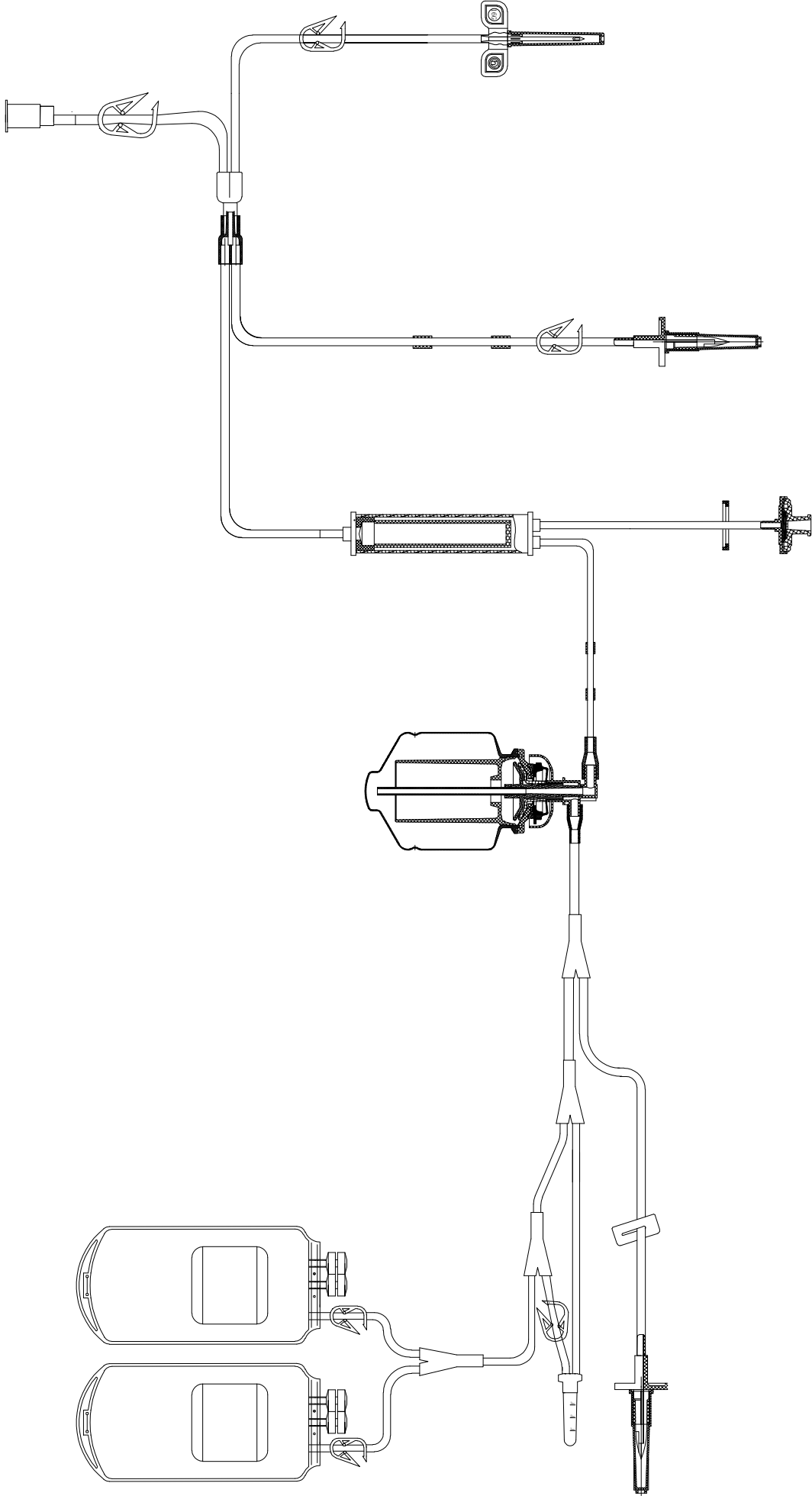
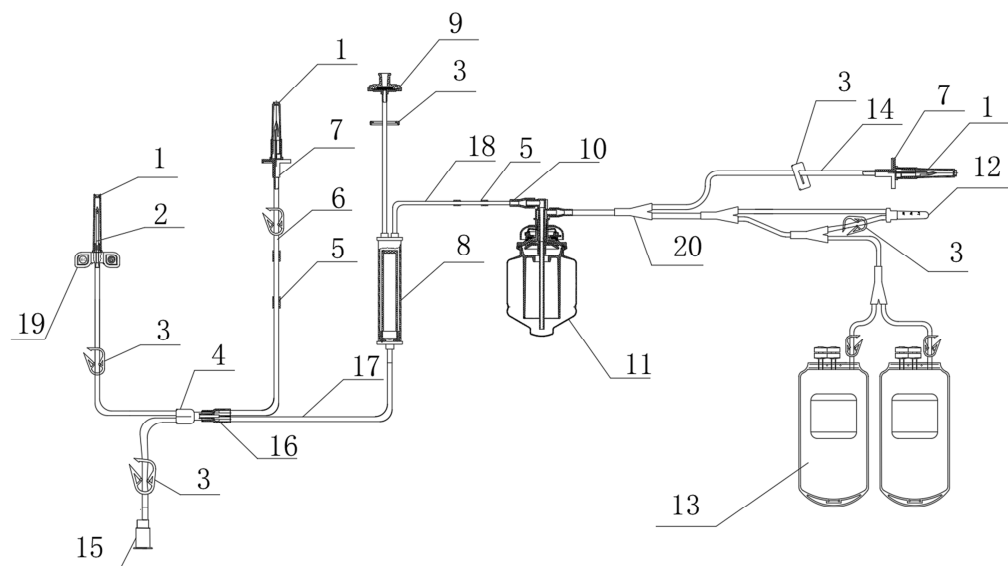


Disposable Plasma Apheresis Kit



Disposable Plasma Apheresis Kit



1、Cover	2、Needle(16Gor15G or 17G)	3、Clamp
4、Three-ways	5、Stopper	6、Pump tubing
7、Puncture outfit	8、Blood Filters	9、DPM
10、Two-way connect	11、Plasma bowl	12、Sampling tube
13、Plasma bag 1000ml	14、Tubing	15、Sampler
16、luer three-ways	17、Tubing	18、Pump Tubing
19、Needle holder	20、Y Three-ways	



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 103097 0002 Rev. 00

Manufacturer:

**Shanghai Dahua Medical
Apparatus Co., Ltd.**

No.85, Shengshan Road
Chongming Industrial Zone
202150 Shanghai
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Disposable Centrifugal Plasma Separator System,
Disposable Platelet Apheresis System,
Plasma Collection Machine**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

SH19145101

Valid from:

2019-11-08

Valid until:

2024-05-26

Date,

2019-11-08

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 103097 0002 Rev. 00

Facility(ies):

Shanghai Dahua Medical Apparatus Co., Ltd.
No.85, Shengshan Road, Chongming Industrial Zone, 202150
Shanghai, PEOPLE'S REPUBLIC OF CHINA



质量管理体系认证证书

兹 证 明

上海达华医疗器械有限公司

统一社会信用代码: 91310230134430145R

中国 上海崇明工业园区崐山路 85 号 202150

建立和实施的质量管理体系符合:

YY/T0287-2017/ISO 13485:2016

体系覆盖范围:

一次性使用输血器、一次性使用离心式血浆分离器、一次性使用血液透析管路、
一次性使用血小板分离器 (仅供出口)、单采血浆机、女用避孕套及其润滑剂 (以上产品按医疗器械注册证范围)、引流袋 (按医疗器械备案凭证范围) 的设计、生产。

审核地点: 上海市崇明区崇明工业园区崐山路 85 号 4 幢 B 区、5 幢 A 区

本证书注册编号: SAC20Y10007R1M

证书有效期: 2020 年 12 月 02 日至 2023 年 12 月 01 日

本证书的有效性依据年度监督审核获得保持

蒋平

认证机构



2020 年 12 月 02 日

上海质量体系审核中心

中国 上海市武夷路 258 号 <http://www.sac.org.cn>

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R

No.85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

has established and applied a quality management system in conformity with

YY/T0287-2017/ISO 13485:2016

The scope covered by the system is:

design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems, disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only), plasma collection machine, woman's condom and lubricant (above products shall be limited in its qualification certificate), drainage bags (shall be limited in its qualification certificate).

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: SAC20Y10007R1M

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.



Certification Body

Date Dec.02, 2020

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R. China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of Certification and Accreditation Administration of the People's Republic of China (CNCA).



质量管理体系认证证书

上海达华医疗器械有限公司

统一社会信用代码: 91310230134430145R

中国 上海崇明工业园区峨山路 85 号 202150

建立和实施的质量管理体系符合:

GB/T 19001-2016/ISO 9001:2015

体系覆盖范围:

一次性使用输血器、一次性使用离心式血浆分离器、一次性使用血液透析管路、一次性使用血小板分离器 (仅供出口)、单采血浆机、女用避孕套及其润滑剂 (以上产品按医疗器械注册证范围)、引流袋 (按医疗器械备案凭证范围) 的设计、生产。

审核地点: 上海市崇明区崇明工业园区峨山路 85 号 4 幢 B 区、5 幢 A 区

本证书注册编号: 00320Q30395R1M

证书有效期: 2020 年 12 月 02 日至 2023 年 12 月 01 日

本证书的有效性依据年度监督审核获得保持

陈平



认证机构

2020 年 12 月 02 日



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C003-M

上海质量体系审核中心

中国 上海 武夷路258号 <http://www.sac.org.cn>

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R

No.85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

has established and applied a quality management system in conformity with

GB/T 19001-2016/ISO 9001:2015

The scope covered by the system is:

design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems, disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only), plasma collection machine, woman's condom and lubricant (above products shall be limited in its qualification certificate), drainage bags (shall be limited in its qualification certificate).

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: 00320Q30395R1M

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.

Tan Peng

Certification Body



Date Dec.02, 2020



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C003-M

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of

Certification and Accreditation Administration of the People's Republic of China (CNCA)



QUALITY MANAGEMENT SYSTEM CERTIFICATION OF CONFORMITY

Shanghai Dahua Medical Apparatus Co., Ltd.

Unified Social Credit Code: 91310230134430145R
No. 85 Shengshan Road, Chongming Industrial Park, Shanghai 202150, China

**has established and applied a quality management system in conformity with
ISO 9001:2015**

The scope covered by the system is:

*design, production for disposable blood transfusion sets, disposable centrifugal plasma separator systems,
disposable Hemo-dialysis tubing sets, disposable platelet apheresis systems (export only),
plasma collection machine, woman's condom and lubricant (above products shall be limited in its
qualification certificate), drainage bags (shall be limited in its qualification certificate).*

Audit Address: Zone B of Building 4, Zone A of Building 5, No.85 Shengshan Road, Chongming Industrial Park, Chongming District, Shanghai

Certificate Registration: ANAB20Q3037791/1

Duration of Validity: 2020.12.02—2023.12.01

The validity of this certificate will be maintained through annual surveillance audit.

Tang Ping

Certification Body



Date Dec.02, 2020



Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>

This certificate information can be found at the official website (www.cnca.gov.cn) of
Certification and Accreditation Administration of the People's Republic of China (CNCA)



上海市达华医疗器械有限公司
Shanghai Dahua Medical Apparatus Co.,Ltd



Manufacturer Information

Registration address: No.85 Shengshan Road, Chongming Industrial Zone,Chongming County, Shanghai

Zip code: 202150

Manufacturer: Shanghai Dahua Medical Apparatus Co.,Ltd.

Manufacturing address:Changzheng Farm,Chongming County, Shanghai

Zip code: 202174

Tel: 021-63767228, 59311357

Fax: 63761666



Introduction of Dahua Medical

Established in 2000, Shanghai Dahua Medical Apparatus is a modern high-tech enterprise which is engaged in researching, developing and technology introducing related to blood separation technology , medical apparatus and assorted consumptive materials. From 2003 to now, Shanghai Dahua Medical Apparatus enjoys the reputation of Shanghai high-tech enterprise. Several products manufactured by Shanghai Dahua are entitled as national and municipal key products, Shanghai high-tech achievements conversion projects, Shanghai Torch plan, small and medium size enterprises technology innovation projects and Shanghai progress prize in science and technology.

Dahua has over 20 years of management and production experience of disposable medical equipment. It has a high quality and well-experienced team of science and technology development, production and management that familiar with GMP standard and quality guarantee. It has strong technical development capabilities as well as strong management ability in project research and development and industrialized implementation. It is a big production enterprise in domestic blood transfusion technique field.

It possesses 51 patents including 15 invention patents. A number of products are named Shanghai and national key new product. The company has two factories in Chongming with a land area of 61,270 square meters. The new factory is located at Chongming Industrial Park, one of the municipal industrial parks in Shanghai, with a land area of 33,333 square meters and a floor space of 40,000 square meters.

DAHUA is executive director of the Association of the National Medical Polymer; director of the Chinese Society of Blood Transfusion; member of the Standards Committee of the Chinese family planning appliances; China the medical polymer Standards Committee members; Shanghai Medical Device Industry.

◆ Association executive

Experience from cooperating with international organization

Dahua has accumulated rich experience in market development and quality control from cooperating with Bill and Melinda Gates Foundation and PATH in woman condom project.

◆ **Certificates:**

Comply to ISO13485:2016 / ISO9001:2015

GMP certification of medical device by Chinese SFDA

CE Marking of TUV company, Germany

SABS Marking of South Africa

UNFPA/WHO Pre-qualification

ANVISA GMP certificate of Brazil

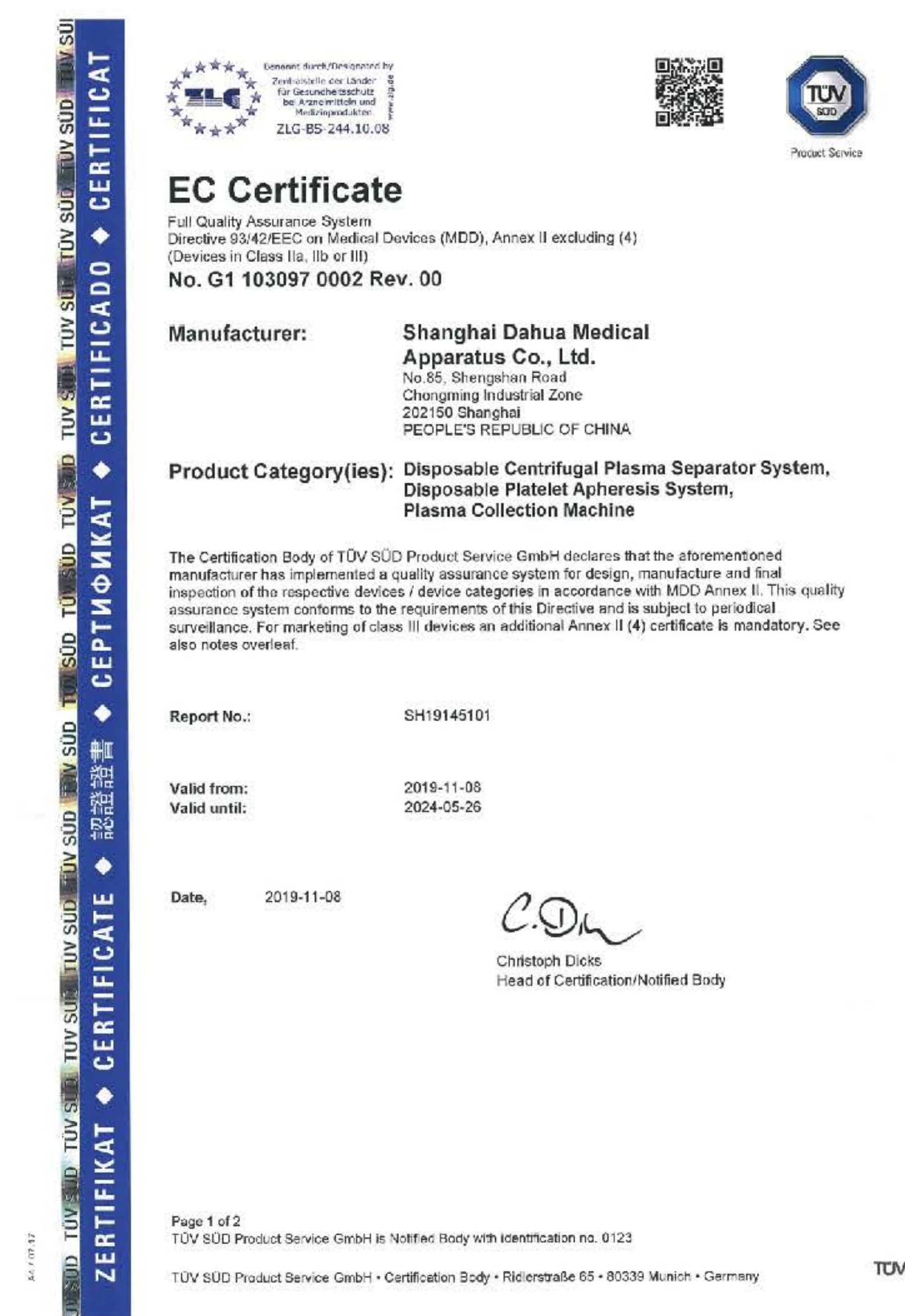
Cuba MOH registered

Belarus MOH Registered

Pakistan MOH Registered

Iran MOH Registered

Ukraine MOH Registered



Plasma Collection Machine



◆ Type

DHIJ-I

◆ Intended use

The DHJ-I plasma collection machine with the software is combined with a disposable plasma separator and a tubing to form a plasma collection system for non-in vitro plasma collection of the human body. The collected plasma will be used in the production of human serum albumin or to supplement coagulation factors or massive blood loss of patients. At the same time, the device can also be used for therapeutic plasma exchange and component therapy.

◆ Advantage

- ◎ multi-languages
- ◎ Touchable display screen and reliable operation panel
- ◎ Clear human-machine interface, excellent human-machine communication
- ◎ Stable speed of centrifuge, 7000 +/- 50 RPM to ensure the quality of the plasma
- ◎ Shorter Collection time to improve the work efficiency
- ◎ Control system modularization; A relative small dimension; easy for maintaining
- ◎ Display main working parameter
- ◎ Automatic electronic scale correction function to ensure high collection standard.
- ◎ Complete warning system
- ◎ Remote control and data transmission: through net and scan function, human can monitor running state, operational parameter of storage device and print statistic report.(optional)
- ◎ Scanning function to automatically record the operator and donor's ID , Disposable information (optional)
- ◎ Printing function to print collection data without human writing to ensure the accurate data(optional)
- ◎ Remote fault diagnosis: through remote fault diagnosis, engineer can maintain device.
- ◎ The design of outlook is to ensure user can use device easily, safely. Light appearance does not occupy space; suit for collection vehicle.V

◆ Specification

Size Length*Width*Height	50*34*37(cm)	Package size : 73*51*43 (cm)
Weight	Net : 32kg	Gross : 36kg
Input	Voltage range; : 230VAC,frequency range:50/60Hz,Input power : 420W	
Working condition	Atmospheric pressure	86kPa ~ 106kPa
	Ambient temperature	+10°C ~ +30°C
	Relative humidity	≤70%
	The RF signals emitted by the high-power communication base station and similar equipment may cause interference and influence to the DH-PCM. Therefore, the similar equipment should not be too close to the DH-PCM, User should avoid using those equipment during the DH-PCM running.	

Disposable Centrifugal Plasma Separator System



◆ Product Intended use

Plasma collection system is formed by Disposable centrifugal plasma separator system and plasma collection machine ,which is used to collect the plasma of human body.
The collected plasma will be used in blood biologics to produce human albumin or to supplement the patient's blood coagulation factors or massive blood loss. At the same time, the product can also be used for therapeutic plasma exchange and component therapy.

◆ Matched model

This product is suitable for the Disposable Centrifugal Plasma Separator System of Dahua orHaemonetics PCS2 type or similar function.

◆ Applicable people

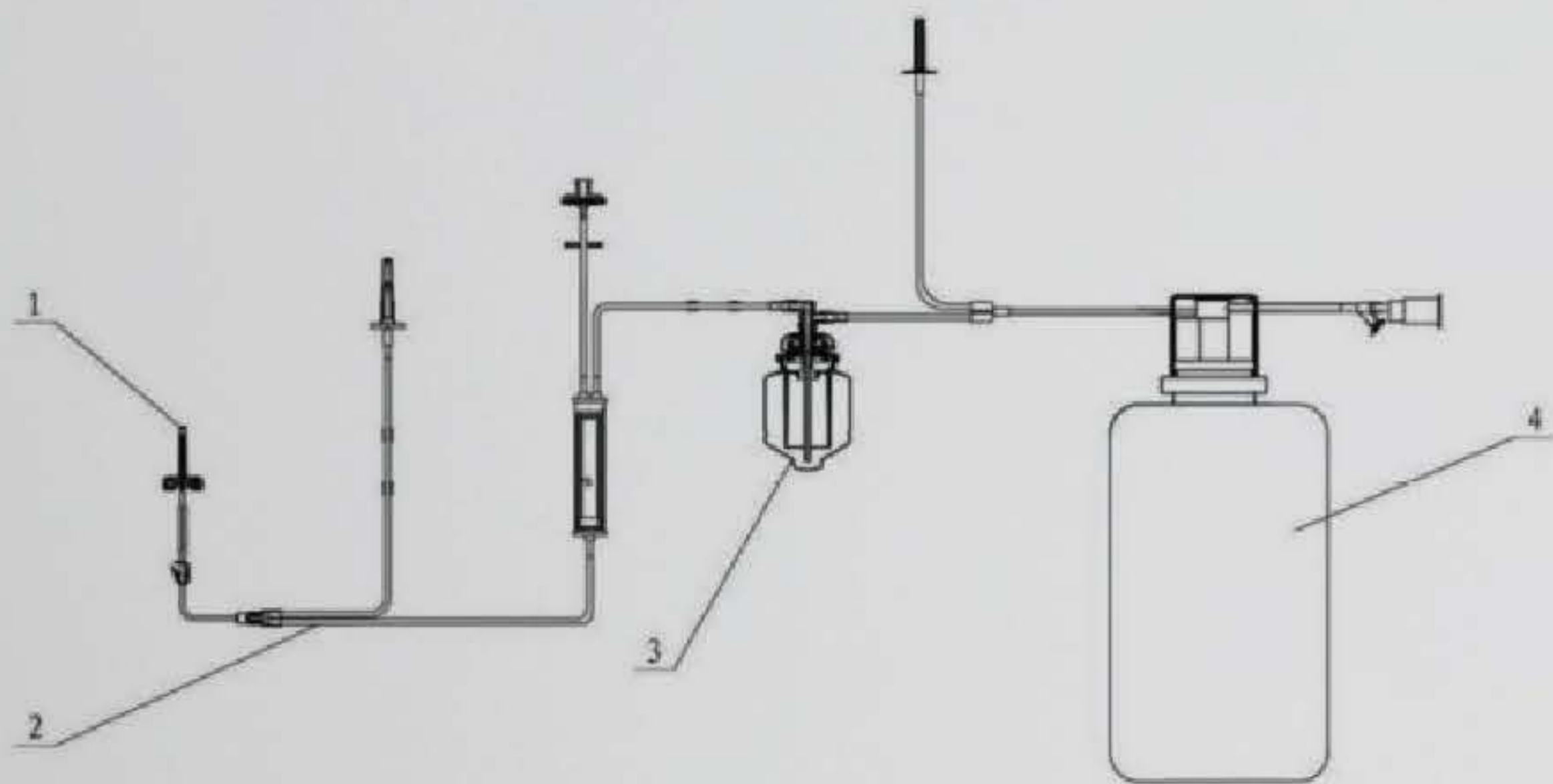
Healthy people (except infants, pregnant and lactating women)

◆ Product model

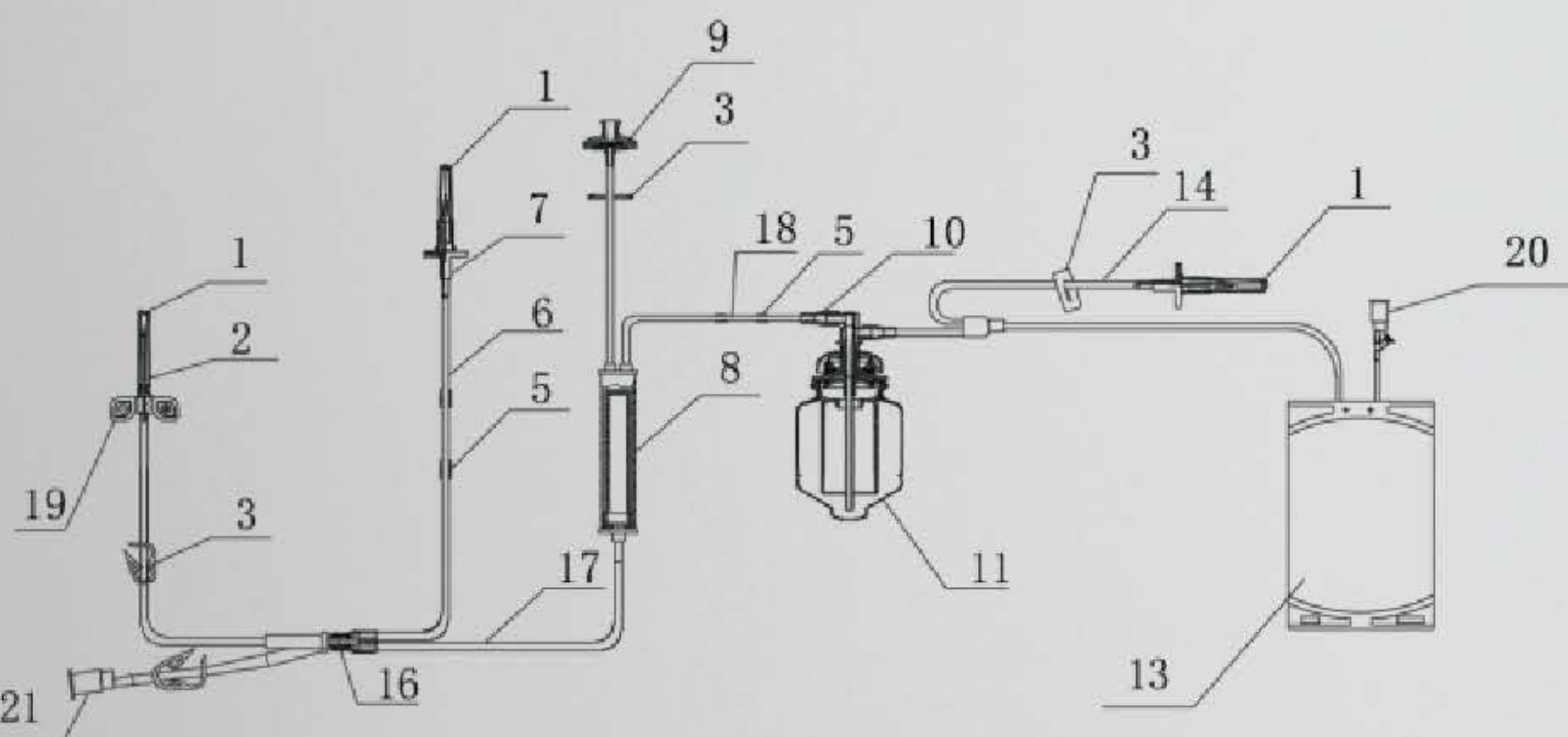
FLQ-4J-1~15; FLQ-1J-1~8; total 23 models

◆ Product specifications

1000ml (bottle or bag capacity)



1.Apheresis needle	2.Apheresis Tubing set
3.Plasma collecting bowl	4.Plasma collection container



1. Cover	2. 15G,16G,17G(needle)	3. Clamp
5. Clip	6. Pump tubing	7. Puncture outfit
8. Blood Filters	9. DPM	10. Two-way connect
11. Plasma separator cup	12. Sampling tube	13. Plasma bags
14. Tubing	16. Lure three-ways	17. Tubing
18. Pump tubing	19. Needle handle	21. Sampler



Disposable Platelet Apheresis System



◆ Product Intended use

This product is matched with the full-automatic centrifugal blood cell collection instrument, which is used to collect the blood of human body, separate and store human platelets, and also transfuse cells.

◆ Matched model

This product is suitable for the automatic centrifugal blood cell collection equipment of Dahua or Haemonetics MCS+ type or similar Brand.

◆ Applicable people

Healthy people (except infants, pregnant and lactating women)



◆ Product mode

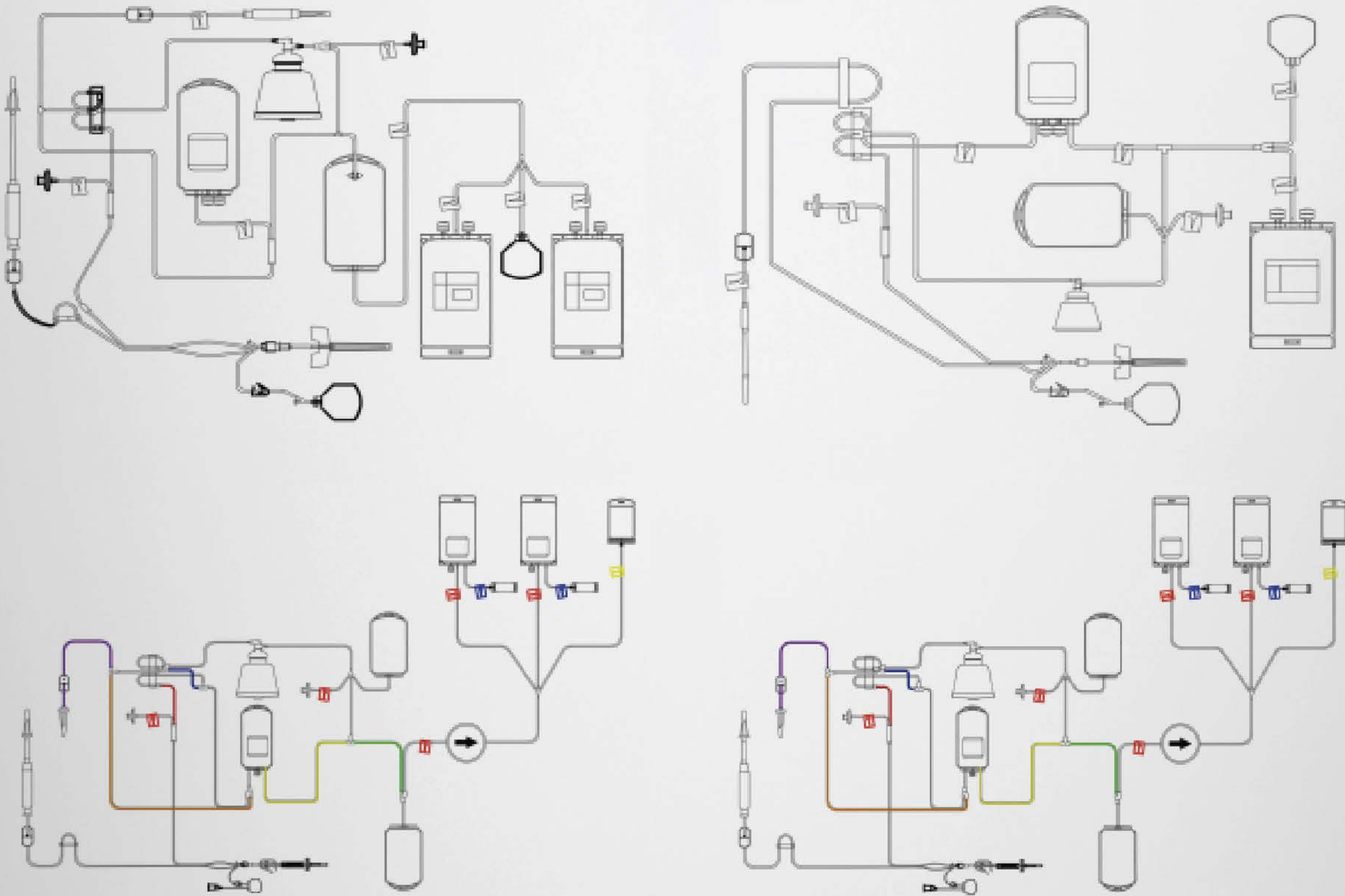
Product Type	Equipment Type
XXBFLQ1-800+XXBFLQ2-300	HaemoneticsMCS+ 3P
XXBFLQ1-800-1+XXBFLQ2-300	HaemoneticsMCS+System
XXBFLQ1-800-2+XXBFLQ2-300	HaemoneticsMCS+
XXBFLQ1-800-3+XXBFLQ2-300	HaemoneticsMCS+System
XXBFLQ1-800-4+XXBFLQ2-300	HaemoneticsMCS+ 3P
XXBFLQ1-5-800+XXBFLQ2-300	HaemoneticsPCS+

◆ Product composition

Centrifugal cup, Platelet apheresis tubing set

◆ Product Structure

See Typical product



Disposable hemodialysis set

◆ Product Intended use

Hemodialysis treatment is to treat acute or chronic renal failure patients, artificial simulation of the working principle of renal function, through dialysis treatment, that is, to clear the toxins in the body, correct various disorders caused by toxins and drain the accumulated water in the body, so that the physiological indicators of the patients return to normal state.



◆ Matched model

This product is suitable for Fresenius, Gambro, B. Braun or similar hemodialysis equipment

◆ Product model

Model	Pump tube size (arterial line) (inner * outer * length)	Outer diameter of blood filter/ Outer diameter of the bubble filter	Arterial line Prime volume	Venous line Prime volume
A004/V604	8*12*300mm	φ22mm/φ22mm	105ml	76ml
A006/V601	6.35*9.75*380mm	φ22mm/φ22mm	95ml	78ml
A007/V607	8*12*370mm	φ22mm/φ22mm	96ml	76ml
A008/V608/V609	3.3*6.3*185mm	φ20mm/φ20mm/φ20mm	65ml	25ml/25ml
A010/V610	8*12*380mm	φ20mm/φ20mm	86ml	33ml
A013/V613	8*12*300mm	φ22mm/φ22mm	103ml	80ml
A014/V616	8*12*380mm	φ22mm/φ22mm	105ml	72ml
A015/V613	6.35*9.75*420mm	φ20mm/φ20mm	88ml	80ml
A016/V616	6.35*9.75*300mm	φ20mm/φ22mm	95ml	72ml
A017/V600	8*12*360mm	φ22mm/φ22mm	105ml	80ml
A018/V612	6.35*9.75*380mm	φ20mm/φ20mm	64ml	76ml
A019/V616	8.0*12.0*360mm	φ22mm/φ22mm	100ml	72ml
A020/V611	6.35*9.75*175mm	φ22mm/φ22mm	90ml	63ml
A029/V607	8.0*12.0*300mm	φ22mm/φ22mm	103ml	76ml
A030/V613	8.0*12.0*420mm	φ22mm/φ22mm	88ml	80ml
A031/V602	6.35*9.75*370mm	φ22mm/φ22mm	105ml	76ml
A032/V611	6.35*9.75*370mm	φ22mm/φ22mm	96ml	63ml
A035/V613	8.0*12.0*380mm	φ22mm/φ22mm	105ml	80ml

◆ See Typical product

