

Nanjing Shuangwei Biotechnology Co., Ltd.



A reliable medical device manufacturer and service provider specialized from 1993!

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ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICATE



EU Quality Management System Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I(a) and Class IIb Devices)
No. G10 109472 0004 Rev. 00

Manufacturer: Nanjing Shuangwei Biotechnology Co., Ltd.
No 123, Huakang Road, Jiangbei New Area
210000 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA
SRN Manufacturer - CN-MF-00023311

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Erfenstrasse 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant C.S. harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodic surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert/?q=cert.G10.109472.0004.Rev.00

Report No.: B.J21088903
Valid from: 2024-01-10
Valid until: 2029-01-09

Issue date: 2024-01-10


Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH - Certification Body - Riederstraße 65 • 80339 Munich • Germany



✓ Medical Device Manufacturing License

✓ Medical Device Operating License

✓ ISO9001

✓ ISO13485

✓ MDR CE

✓ MDSAP

✓ ANVISA

✓ ISO11135



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Nanjing Shuangwei Biotechnology Co., Ltd.
No.123, Huakang Road
Jiangbei New Area
Nanjing
Jiangsu
210000
China

Facility ID Number: F006123

Holds Certificate No: **MDSAP 764394**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHFW MD No 169 (2004), as amended by MHFW MD No 56 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and development, production and distribution of Orthopaedic external fixation devices; Blood transfusion devices; Wound dressings and drainage devices; Catheters for clinical emergency treatment and the establishment of artificial airways; Disposable prostatic dilation catheters.

For and on behalf of BSI: 
Graeme Turbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-11-21 Effective Date: 2024-02-07 Expiry Date: 2025-11-20

 BSI Group America Inc. is an MDSAP recognized auditing organization

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„making excellence a habit“

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/Clients/verify. To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Wolkrite Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

02

Product & Service

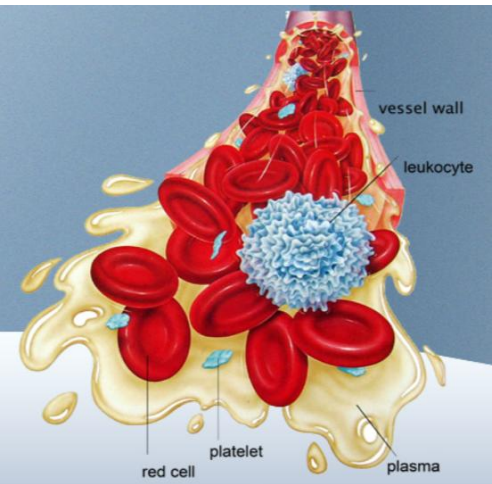
Safe Blood Transfusion

Wound Therapy



- Leukocyte Reduction Filter (for Blood)





**Whole
Blood**

Plasma

water

**Plasma proteins, sugars, vitamins, hormones,
metabolites and inorganic salts, etc.**

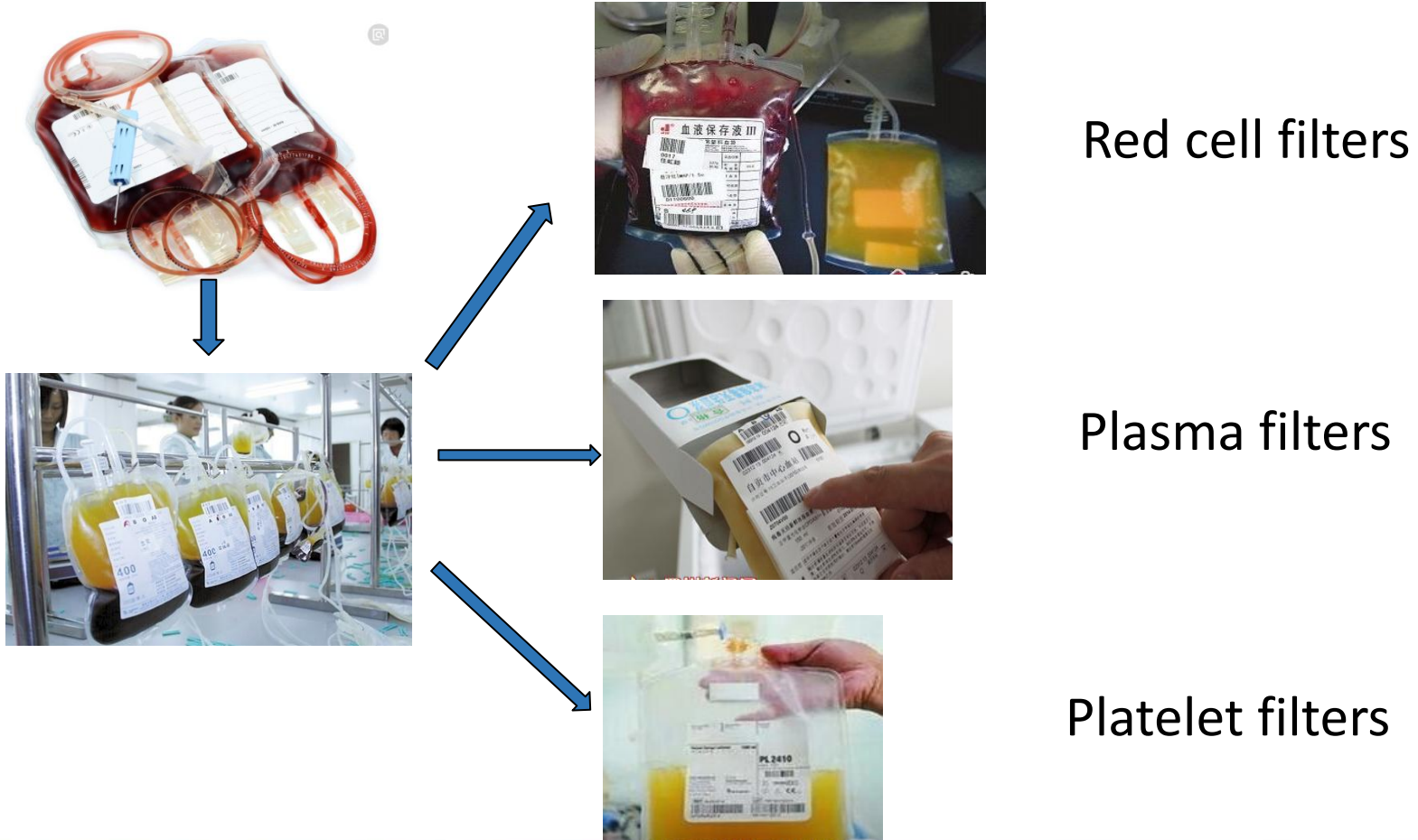
Blood cell

white blood cell (leukocyte)

Platelet

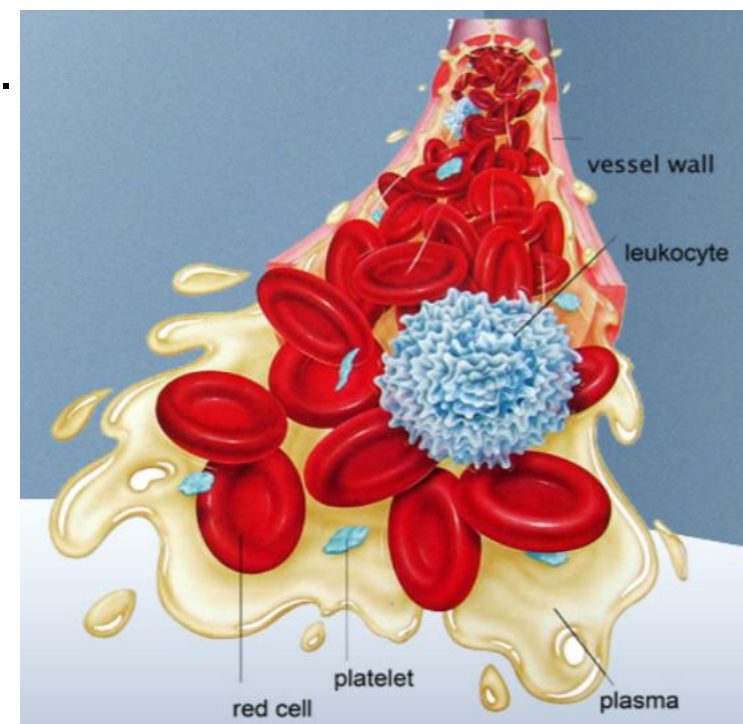
red blood cell

Complete range of leukocyte filters for all blood components



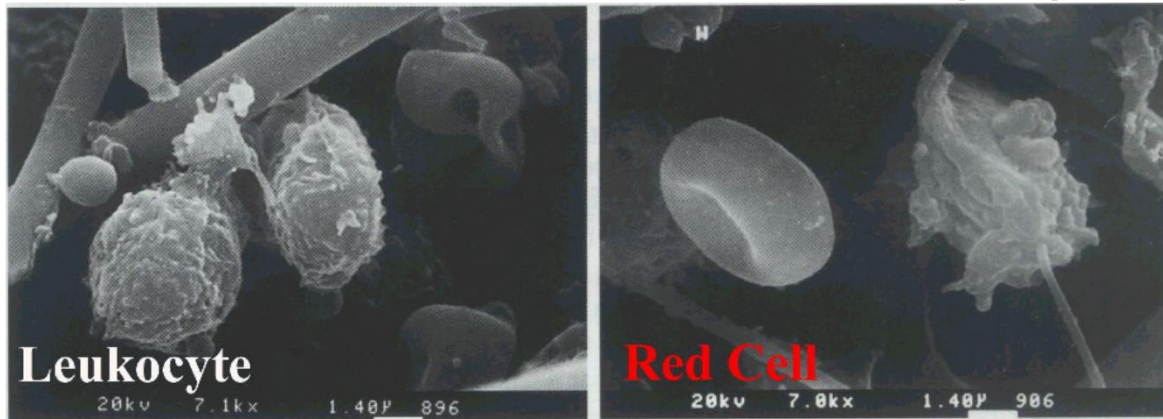
Why should the leukocyte be filtered out?

- Prevent febrile nonhemolytic transfusion reactions (FNHTR).
- Prevent HLA alloimmunization.
- Reduce the rate of CMV (cytomegalovirus) , T-lymphocyte virus- I infections.
- Reduce the rate of ineffective platelet transfusion.
- Prevent adult respiration distress syndrome (ARDS).
- Prevent graft-versus-host disease to certain degree.



Filtration Mechanism

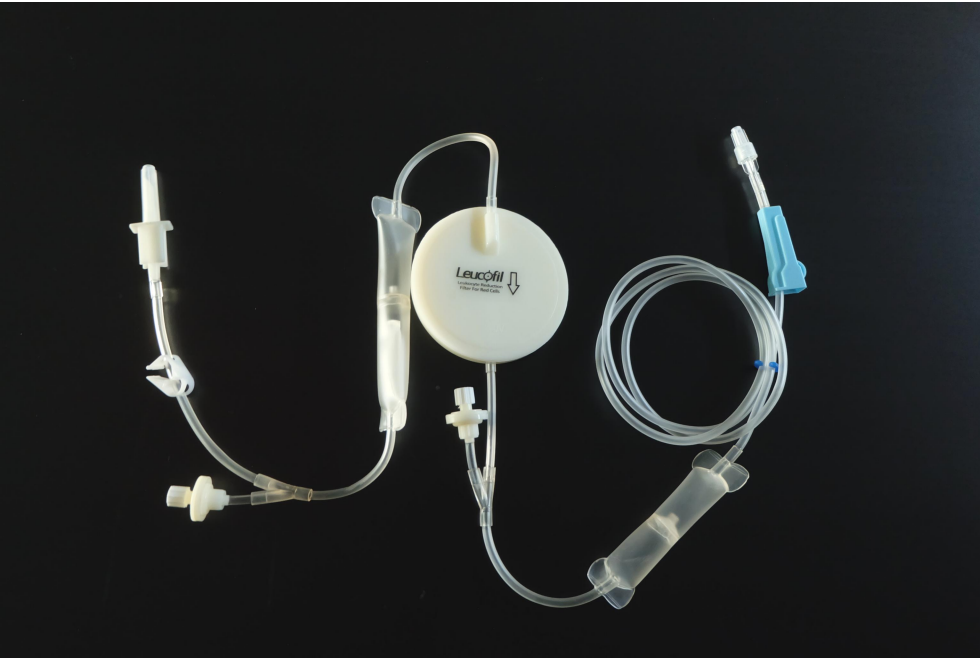
SHUANGWEI series of filters are combination of depth fiber and adsorption fiber, where leukocytes are excluded and entrapped by the fibers, and the leukocytes adhere to the fibers due to their properties.



Leukocytes are blocked
and adsorbed

Red cells pass the
membrane after
deformation

01



Type: For bedside use, with Male conical fitting

For Blood Components: red cell

Model: FTS-RC102

Intended Use: It is used to filter out leukocytes and microaggregates from red cells. Patients can receive leukoreduced red cell transfusion on medical bed or chair.

Application Occasion: Hospital

Performance:

- 1、Residual WBC in red cell: $< 1 \times 10^6$;
- 2、Recovery rate of red cell: $\geq 85\%$;
- 3、100% filter out microaggregates.

02



Type: For bedside use, with Male conical fitting

For Blood Components: red cell

Model: FTS-RC101

Intended Use: It is used to filter out leukocytes and microaggregates from red cells. Patients can receive leukoreduced red cell transfusion on medical bed or chair.

Application Occasion: Hospital

Performance:

- 1、Residual WBC in red cell: $< 1 \times 10^6$;
- 2、Recovery rate of red cell: $\geq 85\%$.

03



Type: For blood center/blood bank use, with 500ml transfer bag

For Blood Components: red cell

Model: FTS-RC202

Intended Use: It is used to filter out leukocytes and microaggregates from red cells. The leukoreduced red cells can be stored for later use.

Application Occasion: Blood Center, Blood Bank

Performance:

- 1、Residual WBC in red cell: $< 1 \times 10^6$;
- 2、Recovery rate of red cell: $\geq 85\%$;
- 3、100% filter out microaggregates.

04



Type: For bedside use, with Male conical fitting

For Blood Components: platelet

Model: FTS-PL110

Intended Use: It is used to filter out leukocytes and microaggregates from 4-6 units platelets or equivalent apheresis platelets. Patients can receive leukoreduced platelet transfusion on medical bed or chair.

Application Occasion: Hospital

Performance:

- 1、Residual WBC in platelet: $< 1 \times 10^6$;
- 2、Recovery rate of platelet: $\geq 85\%$;
- 3、100% filter out microaggregates.



Type: For blood center/blood bank use, with 1000ml transfer bag

For Blood Components: platelet

Model: FTS-PL210

Intended Use: It is used to filter out leukocytes and microaggregates from 4-6 units platelets or equivalent apheresis platelets. The leukoreduced platelets can be stored for later use.

Application Occasion: Blood Center, Blood Bank

Performance:

- 1、Residual WBC in platelet: $< 1 \times 10^6$;
- 2、Recovery rate of platelet: $\geq 85\%$;
- 3、100% filter out microaggregates.