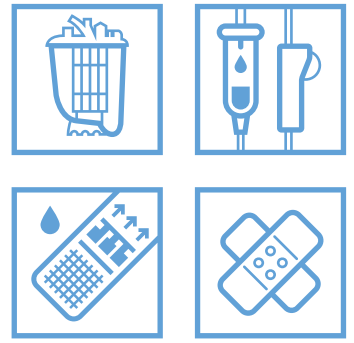


Sefar Healthcare

Safety Filters & Hydrophilic Solutions



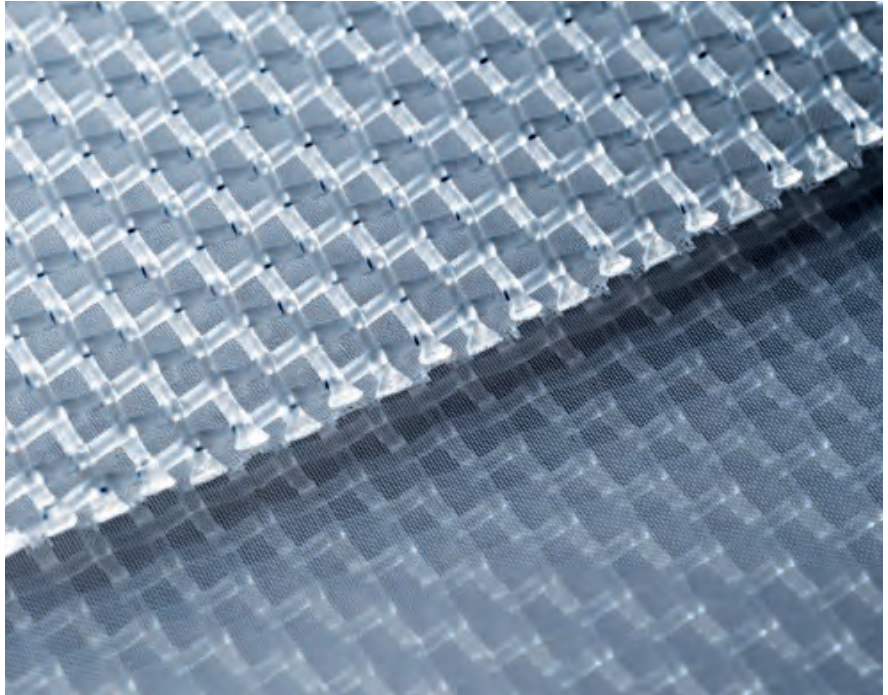
Filter Components

S E F A R
■ ■ ■ ■

Sefar Healthcare

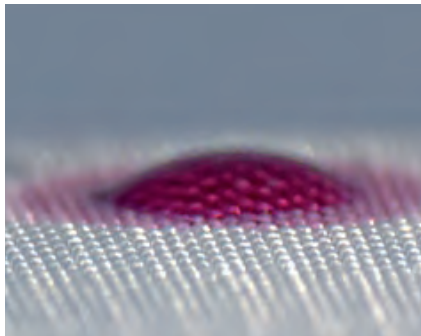
Filtration Solutions

SEFAR MEDIFAB® open mesh fabrics are woven structures composed of monofilament yarns, typically polyester (PET) and polyamide (PA). The materials are FDA-compliant and are utilized for medical filtration and diagnostic applications. SEFAR MEDIFAB® fabrics pass all relevant biocompatibility tests of USP Class VI and ISO 10993. In addition certified tests prove that SEFAR MEDIFAB® fabrics are non-cytotoxic, non-hemolytic, non-pyrogenic and show no sensitization. These highly precise and biocompatible filter fabrics are known for their high throughput rates and excellent particle retention efficiencies. Sefar offers the widest available selection of materials in many different weave types and fabrications.



Two layer open mesh fabric SEFAR MEDIFAB®

The SEFAR MEDITEX® product lines offer solutions for healthcare applications with specific requirements. Characteristics of these media include properties such as hydrophilic surfaces (HPL), a specific color (COL), multiple layers (ACC), or structures such as knitted fabrics (KNT). All functional and biocompatible properties are tailored according to customer's requirements.



Hydrophilic SEFAR MEDITEX® HPL NC fabric for diagnostics



Colored SEFAR MEDITEX® COL fabric for blood filtration

Continuous innovation, superior manufacturing processes, a global distribution system and short response times make Sefar the leading supplier of filter components for medical devices. With the weaving process being certified according to ISO 9001 and ISO 13485 along with an ISO 14644 class 7 cleanroom converting, the major medical device manufacturers choose Sefar's products and worldwide partnership.



Class 7 cleanroom according to ISO 14644

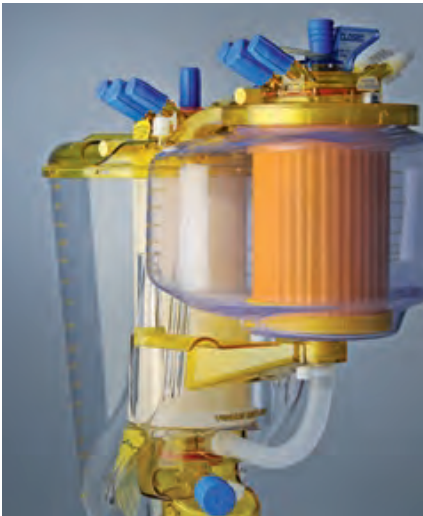
Sefar Healthcare

Cardio Systems

During open-heart surgery, a complex system of medical devices temporarily replaces heart and lung functions. Vital components of this extra-corporal circuit (also called heart-lung machine or cardio-pulmonary bypass) are very precise filters integrated into the venous/reservoirs, oxygenator arterial filters and blood bags.

Sefar's precision woven monofilament fabrics are the industry standards for cardio devices and help guarantee patient safety.

High throughput rates, precise mesh openings and proven biocompatibility of Sefar filters contribute to the excellent reliability and performance of the extra-corporal circuit.



Cardiomy Reservoirs Blood Bags

Cardiomy reservoirs and blood bags are central devices of the extra-corporal blood circuit used during open-heart surgery. The filter fabrics inside these devices serve as highly-precise security filters to reliably block particulate emboli as well as microscopic air bubbles and blood clots.



Oxygenators Venous Reservoirs

During cardio-pulmonary bypass surgery the oxygenator replaces the lung's function by enriching the circulating blood with oxygen and removing carbon dioxide. The venous reservoir acts as a prefilter and ensures a constant blood level. Woven fabrics serve as a security filter to remove air bubbles and particulate matter.



Arterial filters

Arterial filters safely block both air bubbles and particulate emboli. In order to obtain a high filtration performance the filter surface area is increased by pleating. Sefar offers hydrophilic surface treatments to improve the priming properties of arterial filter components.

Sefar Healthcare

Infusion

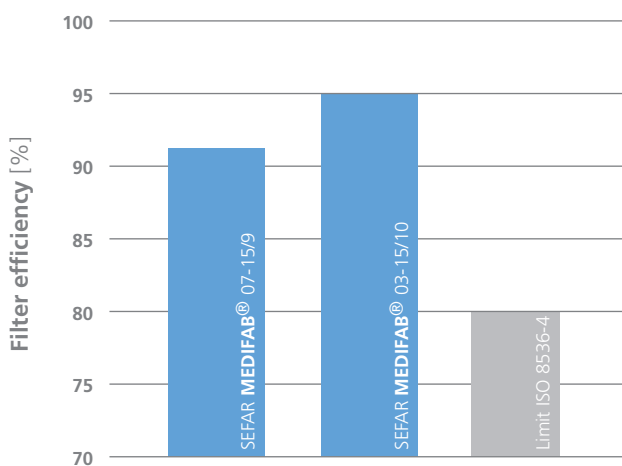
Infusion

The woven fabric in the infusion set acts as a security filter. The function of the filter is to retain large particles that might be present in the infusion solutions (e.g. aggregated nutrients, pharmaceutical compounds) or which may originate from the infusion bag or the infusion bottle. The DIN and ISO standards require that the filter fabric must retain particles greater than 20 microns with an efficiency of greater than 80%.

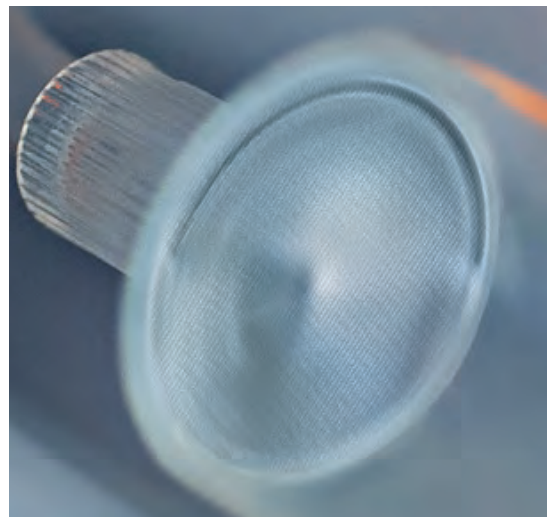
The precision-woven monofilament fabrics of the SEFAR MEDIFAB® product range fulfill and exceed these criteria. Sefar's highly precise and biocompatible filter fabrics are known for their excellent particle retention efficiencies and high throughput rates.



Drip chamber of a standard IV set



Particle retention of NIST traceable monodisperse 20 µm particles



Particle filter of an ISO 8536 compliant IV set

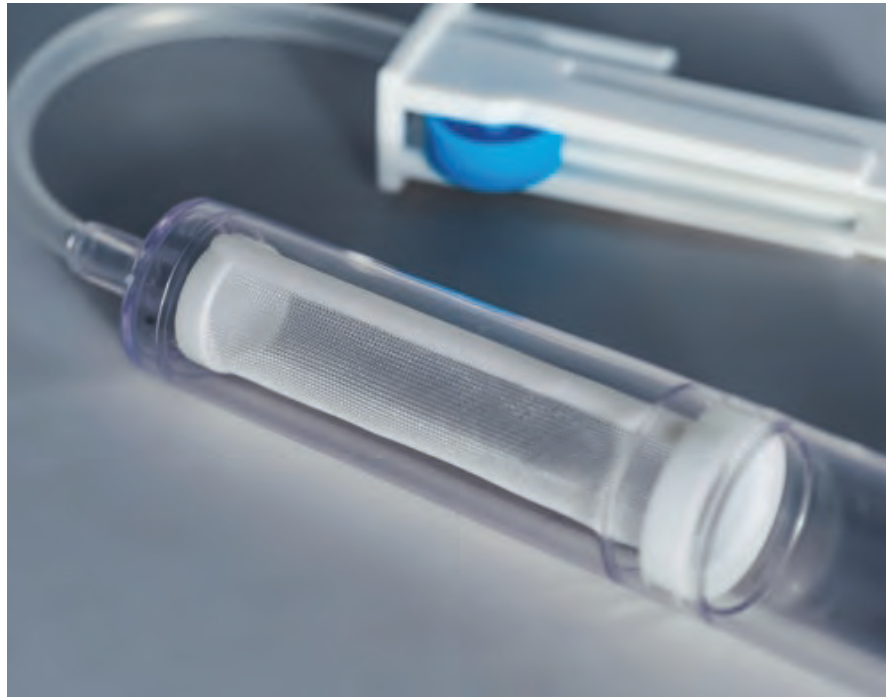
Sefar Healthcare

Transfusion & Diagnostics

Transfusion

Millions of transfusions and auto-transfusions are performed safely every year. Transfusion sets are life-saving devices that prevent blood clots and particles from entering the patient's bloodstream. The high throughput rates and precise mesh openings of Sefar filter fabrics contribute to the excellent reliability and performance of transfusion sets.

Manufacturers like the high strength and consistent filter geometry inherent in Sefar products. Sefar offers the largest range of woven and fabricated medical filter components available.



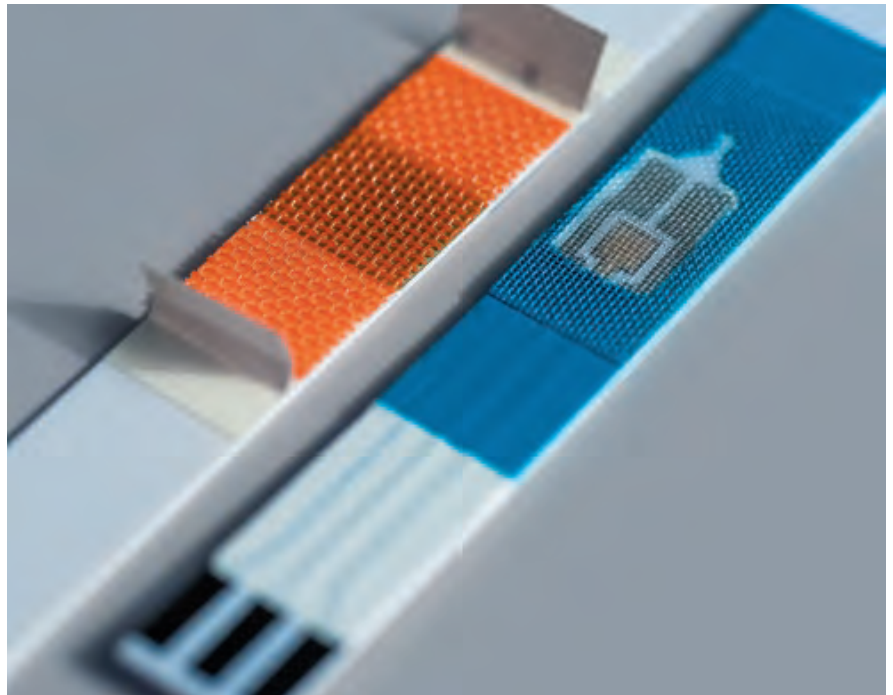
Blood filter in an ISO 1135 compliant transfusion set

Diagnostics

Sefar products increase the speed and reliability of diagnostic test strips. The homogeneous woven structure and hydrophilic surface properties of Sefar fabrics guarantee excellent spreading and wicking performance for even the smallest sample volumes.

A woven fabric enhances the overall performance of a test strip by:

- Increasing flow and lateral flow rate and therefore decreasing response time
- Decreasing sample volume and therefore increasing user acceptance
- Increasing homogeneity of sample distribution and therefore increasing measuring accuracy



Test surface of blood test strips

Sefar Healthcare

Woundcare

Materials

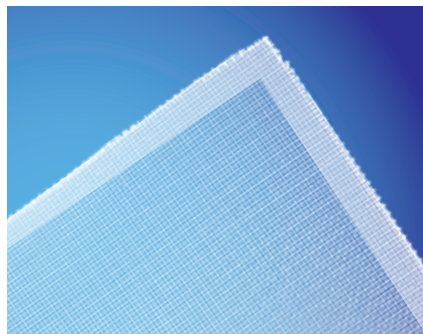
The SEFAR MEDIFAB® product line perfectly meets the requirements of modern and innovative wound management. The materials are woven structures made with PET or PA monofilaments. The proprietary, ISO 13485 certified weaving process results in biocompatible materials that comply with USP VI and ISO 10993 requirements. The materials stand sterilization with all standard methods.

SEFAR MEDIFAB® products have inherently smooth and regular surfaces. The materials are thin (<100 µm) and perfectly transparent. They allow rapid and controlled transfer of exudates. At the same time they do not absorb humidity and maintain a moist wound environment.



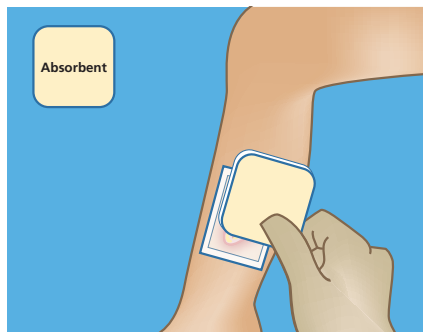
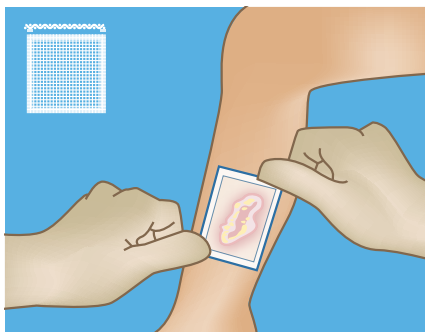
Dispenser and laminated products

As an application example a dispenser facilitates storage and handling of the very soft and flexible dressings. Adhesive frames on the dressings help position the dressing on the wound.



Sefar monofilament shaped part with eudermic adhesive frame positioned on a release liner

Application example for Sefar monofilament fabrics in wound management



Oozing superficial wound

Treatment: Fixed non-adherent contact layer and exchangeable absorbent

Sefar Healthcare

Prefabricated Filter Elements

Sefar owns all processes to convert SEFAR MEDIFAB® fabrics into customer-specific shaped parts.

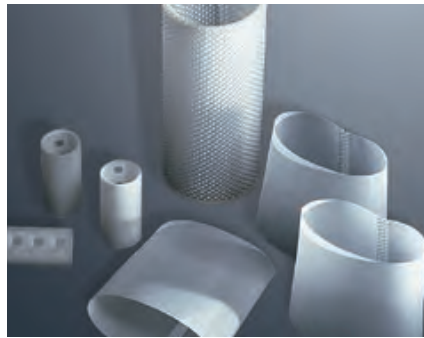
The production in an ISO 14644 class 7 cleanroom is validated according to ISO 9001.



Ribbons

Fabrics can be heat or ultrasonically slit. Both slitting techniques ensure an optimally sealed, non-fraying edge quality. Ribbon width ranges:

- From 7 mm to 2400 mm (heat-slit)
- And from 4 mm to 350 mm (ultrasonically-slit)



Tubes, cut to length

Using either cold or laser cutting, tube segments can be manufactured with the following dimensions:

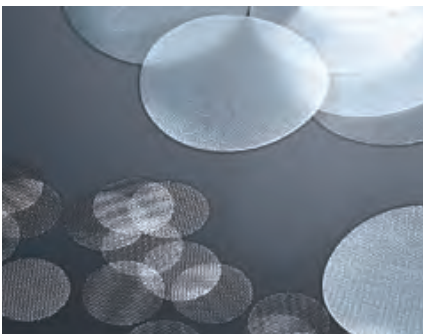
- Cold-cut segments range from Ø 7 mm to Ø 140 mm
- Laser-cut segments range from Ø 7 mm to Ø 80 mm
- Minimal length ranges from 5 mm to 1000 mm



Tubes, continuous rolls

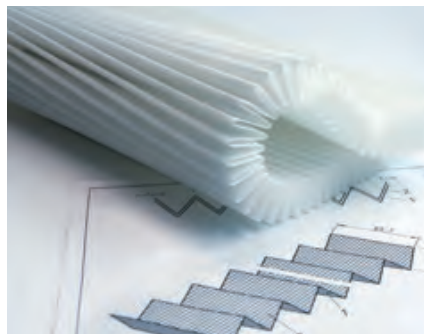
Fabrics, single or multilayer, can be heat slit (transport seam only) or ultrasonically welded into tube configurations:

- Heat-slit tubes range from Ø 8 mm to 50 mm
- US-welded tubes, including micro tubes, range from Ø 3 mm to 250 mm



Stamped discs, shapes

Fabrics can be provided pre-cut in virtually any configuration by laser cutting, cold stamping or ultrasonic stamping. Disc diameter ranges from 6 mm to 95 mm.



Pleated elements

Mono- and multi-layered pleated elements are available in the following dimensions: disc width ranges from 25 mm to 1200 mm and pleat height from 6 mm to 50 mm. Pleat counts are unlimited.



Semi-finished components

Fabrics can be combined with one or several adhesive layers which enables a cost-efficient and fast joining of the fabric piece to any filter component.

Sefar Healthcare

Technical Informations

Sefar's precision-woven monofilament media provide a more consistent material alternative to non-woven media.

For a complete list of SEFAR MEDIFAB® fabrics see «Sefar Solutions for the Healthcare Industry». Upon request, a multitude of other mesh openings and open areas

can be produced. Also, polyether ether ketone (PEEK) and polypropylene (PP) fabrics can be finished in SEFAR MEDIFAB® quality.

The main advantages of Sefar products include:

- Standard material in PET and PA
- Homogenous material properties
- Exceptional lot-to-lot consistency
- Precise fabric dimensions
- Defined surface characteristics
- High throughput rates
- Excellent particle retention efficiencies
- Non-shedding due to monofilament yarn
- High wicking rates due to specific weave constructions
- High wettability due to hydrophilic surface coatings
- EtO- and gamma-sterilizable

The SEFAR MEDIFAB® process and fabrics comply with these regulations and characteristics:

- Code of Federal regulations (FDA 21CFR177) and European guidelines (EU 10/2011)
- Quality systems according to ISO regulations 9001 and ISO 13485 follow applicable GMP guidelines for lot traceability and documentation control
- No ozone depleting substances used in production

SEFAR MEDIFAB® biocompatibility tests comprise:

- Non-pyrogenic according USP
- Non-hemolytic according ISO 8536-4
- Non-cytotoxic according ISO 10993
- USP class VI and ISO 10993 compliant
- Sensitization ISO 10993 compliant
- Low extractables according ISO 1135-4

Abbreviations

FDA & CFR

United States «**F**ood and **D**rug **A**dmistration»; regulatory agency of the US government that is responsible for the regulation of materials used for food production and processing.

Code of **F**ederal **R**egulations and published by FDA, contains/describes guidelines and regulations for food and food related products.



USP

United **S**tates **P**harmacopeia; Organization that promotes and establishes officially recognized standards of quality for drugs and healthcare related articles.



DIN

Deutsches **I**nstitut für **N**ormung (German Institute for Standardization); Organization that promotes and establishes officially recognized standards.



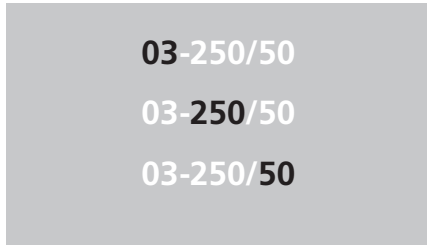
ISO

International **S**tandards **O**rganization; Association that promotes and establishes officially recognized standards.

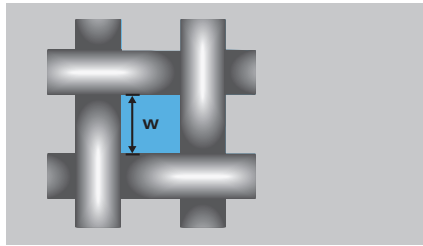


Sefar Healthcare

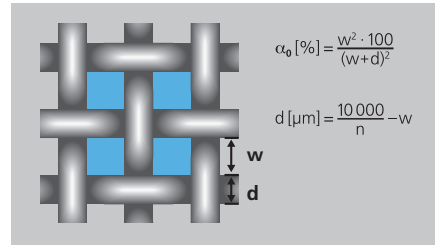
Definitions



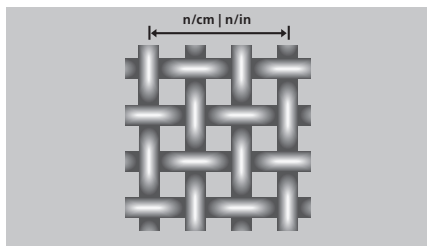
Product reference
Fiber material (03 = PA 6.6) **03-250/50**
Mesh opening [μm] **03-250/50**
Open area (α_o) [%] **03-250/50**



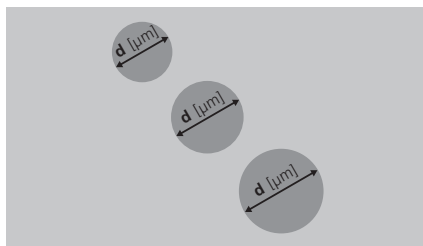
Mesh opening (w) [μm]
The mesh opening **w** is the distance between two adjacent warp or weft threads.
Method: Two-dimensional image analysis
According to: ASTM E11



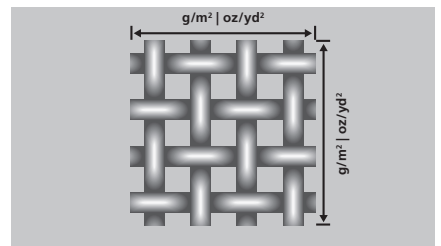
Open area (α_o) [%]
The percentage of the open area α_o is the sum of all mesh openings as percentage of the total fabric area.
Method: Two-dimensional image analysis
According to: ASTM E11



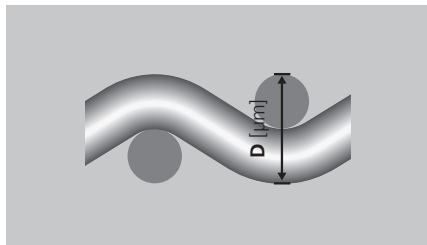
Mesh count (n) [n/cm], [n/in]
The mesh count stands for the number of threads per cm or inch.
Method: Two-dimensional image analysis
According to: ASTM E11



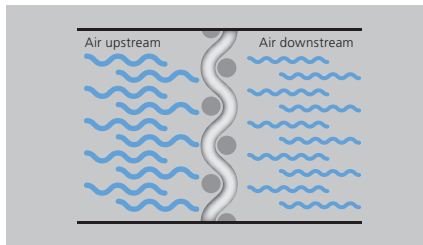
Yarn diameter nominal (d) [μm]
The yarn diameter is measured on the thread before weaving.
Method: Short length method
According to: DIN 53830



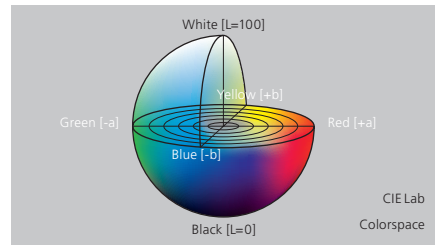
Weight [g/m²] [oz/yd²]
Method: Gravimetry
According to: DIN EN 12127



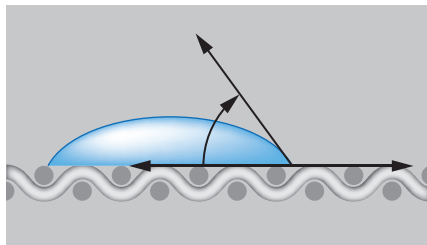
Fabric thickness D [μm]
Method: Thickness gauge
According to: DIN EN ISO 5084



Air permeability
Method: Airflow at pressure drop
According to: DIN EN ISO 9237



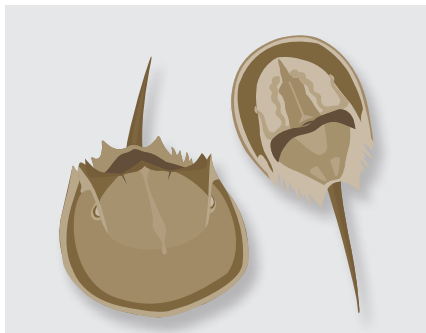
Color [CIE Lab]
Method: Spectral photometry
According to: DIN 5033



Contact angle
Method: Optical image analysis
According to: TAPPI T 558

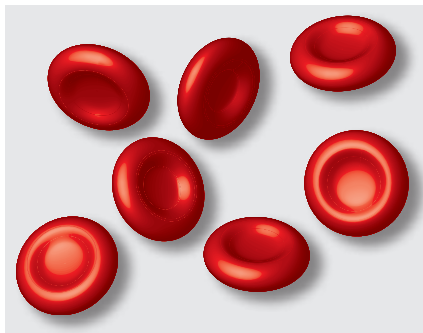
Sefar Healthcare

SEFAR MEDIFAB® Tests



LAL test [Limulus Amoebocyte Lysate or Pyrogen/(Bacterial-) Endotoxin Test] Testing method for detecting bacterial endotoxins which are fever producing, water soluble compounds. Endotoxin is a toxin produced by bacteria and is released after the death of the bacteria.

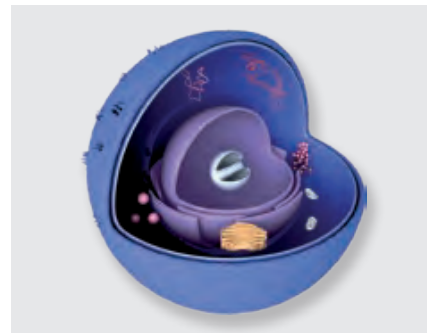
Regulation: US Pharmacopeia (USP) <85>



Hemolysis test

Testing method for detecting compounds which destroy red blood cells.

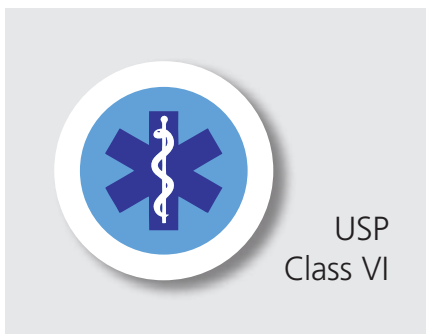
Regulation: ISO 8536-4/ISO 10993-4



Cytotoxicity test

Evaluation of leachables extracted from material which may cause cytotoxicity (cell death).

Regulation: ISO 10993-5



USP
Class VI

Plastics USP class VI test/ISO10993

The tests are conducted in order to evaluate the biocompatibility of materials, i.e. not induce a toxic, injurious or immunological response in living tissue.

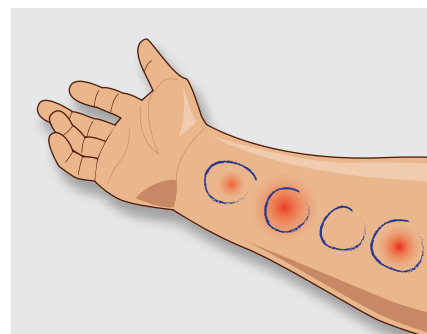
Regulation: USP <88>/ISO10993, parts 5, 6, 10, 11



Acute systemic toxicity

Test for detecting components which may harm the whole organism.

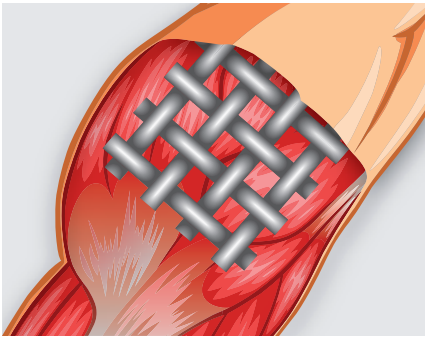
Regulation: USP/ISO10993-11



Intracutaneous toxicity

Evaluation of materials causing intracutaneous toxicity (locally provoked dermal tissue effects).

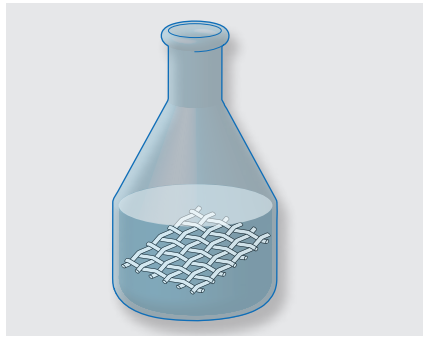
Regulation: USP/ISO10993-10



Implantation test

Evaluation of the potential to be a local irritant or for a toxic response to the material.

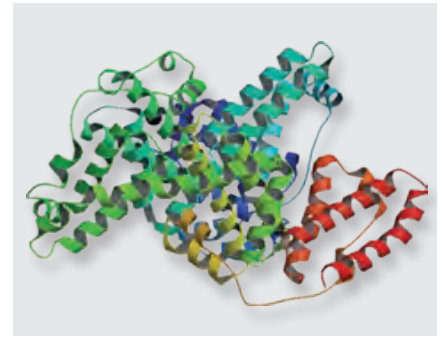
Regulation: USP



Extractables

Evaluation of residues/substances that can be leached from a filter during the filtration process or under other specified conditions.

Regulation: 21CFR177.1500, 21CFR177.1630

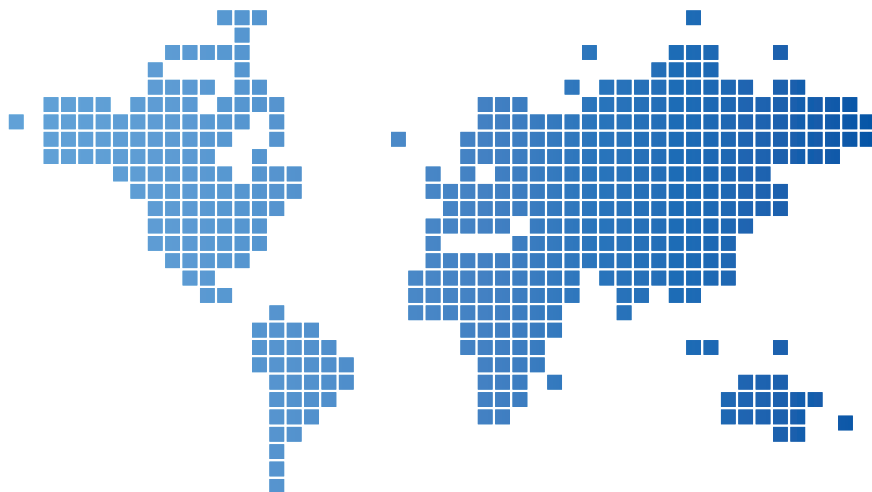


Low protein binding

Bovine Serum Albumin (BSA) adsorption tests prove that SEFAR MEDIFAB® fabrics adsorb BSA at non-detectable levels.

Regulation: Proprietary





Sefar Worldwide

Sefar is the leading manufacturer of precision fabrics from monofilaments for the screen printing and filtration market. Sefar products are used in a wide variety of industries, reaching from electronics, graphics, medical, automotive, food and pharmaceutical applications to aerospace, mining & refining and architecture. With its profound understanding of the applications, Sefar helps its customers to achieve optimum results in their industrial processes. With subsidiaries and representatives around the world, Sefar offers its customers the comprehensive, global support they need.

Headquarters

Sefar AG
Hinterbissastrasse 12
9410 Heiden
Switzerland

Phone +41 71 898 57 00
Fax +41 71 898 57 21

healthcare@sefar.com

<http://healthcare.sefar.com>
www.sefar.com

Africa Contacts

South Africa – Kya Sand
Phone +27 11 708 2485
info@sefarfilterpure.com

Morocco – Casablanca
Phone +212 522 66 14 66
info@sefar.ma

Americas Contacts

USA – Buffalo
Phone +1 800 995 0531
sales@sefar.us

Canada – Saguenay
Phone +1 418 690 0888
info.bdh@sefar.com

Brazil – São Bernardo do Campo
Phone +55 11 4390 6300
contato.brasil@sefar.com

Mexico – Cuautitlan Izcalli
Phone +52 55 2291 0652
info.mexico@sefar.com

Oceania Contacts

Australia – Huntingwood
Phone +61 2 8822 1700
oceania@sefar.com

New Zealand – MT Wellington
Phone +64 9 527 4409
salesnz@sefar.com

Asia Contacts

China – Suzhou
Phone +86 512 6283 6383
info.cn@sefar.com

India – District Thane
Phone +91 9028 656 256
info.in@sefar.com

Malaysia – Johor
Phone +60 7 861 0023
info.my@sefar.com

Singapore
Phone +65 6299 9092
info.sg@sefar.com

South Korea – Seoul
Phone +82 2713 9134
info.kr@sefar.com

Thailand – Bangkok
Phone +66 2 6670 024
info.th@sefar.com

Vietnam – Ho Chi Minh City
Phone +84 2862 925 562
info.vn@sefar.com

Europe Contacts

England – Bury
Phone +44 161 765 3530
sales@sefar.co.uk

France – Lyon
Phone +33 472 13 14 15
vente@sefar.com

Germany – Edling
Phone +49 8071 90400 0
info@sefar.de

Italy – Collegno
Phone +39 011 42 001
info@sefar.it

Netherlands – Lochem
Phone +31 573 744 111
info@sefar.nl

Poland – Poznan
Phone +48 511 467 467
biuro.pl@sefar.com

Spain – Cardedeu
Phone +34 93 844 47 10
info.maissa@sefar.com

Turkey – Ankara
Phone +90 312 287 34 14
info.tr@sefar.com

Important Notice

The products (the «Products») manufactured and sold by any Sefar Group company («Sefar») are not specifically designed, tested or approved for the use in medical implants. Sefar does not make any representation regarding the fitness of the Products for the use in medical implants. If the Products shall be used in medical implants by a manufacturer of medical implants (the «Manufacturer»), it is the sole responsibility of the Manufacturer to ensure compliance with all regulatory requirements and the safety and suitability of the medical implants for which the Products are used. Any and all liability of Sefar and any of its subsidiaries and affiliates arising out of or in connection with the use of the Products in medical implants is expressly excluded. The sale of Products for use in medical implants by Sefar is subject to and conditional upon the execution of a specific undertaking by the Manufacturer confirming its responsibilities. Manufacturers who wish to use the Products in medical implants are kindly requested to contact Sefar.

