Single-Use Filtration and Sensor Solutions
Simplify and Control Your Filtration Processes
### The Fast Solution
Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)
- Sartopore® Platinum, Sartopore® 2, XLM and XLG
- 500 mm TPE tubing
- Opta® MPX Connector

### The Special Solution
Customized solutions for complex assemblies that need to be designed from scratch: Engineer-To-Order (ETO)
Learn more on page 23.

### The Large Solution
Large-Scale Single-Use Filtration Device: Maxicaps® MR
Ready-to-use, pre-assembled, pre-sterilized
Learn more on page 24.
Standard vs. Customized Solutions

**Standardization and Harmonization**
Whether you need simple (PDS) transfer sets or very complex assemblies, such as a PUPSIT (Pre-Use-Post-Sterilization-Integrity-Test) configuration, Sartorius will help you find the perfect design. Our experts can help you standardize and harmonize your single-use world, no matter how complex it seems today.

**Your Options:**
- Simple off-the-shelf standardized options (PDS: Pre-Designed-Solutions)
- Customizable assemblies that come within a few weeks (CTO: Configure-To-Order)
- Complex solutions according to your needs (ETO: Engineer-To-Order)

**Oetiker** Metal Clamp vs. Plastic Cable Tie
All gamma irradiated & autoclaved Filter and Sensor Transfer Sets use Oetiker* clamps.

The metal clamps are wrapped with an innovative silicone rubber band to protect the user and the packaging.

* Oetiker* is a registered trademark of the Oetiker Group.

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### The Fast Solution
**Pre-Designed Solutions (PDS)**

| Filter Elements 100% Tested | 100% Visual Inspection and Batch Record Review | Biocompatibility USP 87 or 88 Class VI | TSE|BSE EMA/410/01 & Reach | Pre-Qualified Connections | Extractables Profile | Assurance of Supply (AoS) ** | ASTM Transport Validation | Approx. Lead Time |
|-------------------------------|-----------------------------------------------|---------------------------------------|----------------------------------------|--------------------------|-------------------------|-----------------------|-------------------------|---------------------|
| ☐                             | ☐                                             | ☐                                    | ☐                                     | ☐                        | ☐                      | ☐                     | ☐                      | 4 weeks             |

**Configure-To-Order (CTO)**

| Filter Elements 100% Tested | 100% Visual Inspection and Batch Record Review | Biocompatibility USP 87 or 88 Class VI | TSE|BSE EMA/410/01 & Reach | Pre-Qualified Connections | Extractables Profile | Assurance of Supply (AoS) ** | ASTM Transport Validation | Approx. Lead Time |
|-------------------------------|-----------------------------------------------|---------------------------------------|----------------------------------------|--------------------------|-------------------------|-----------------------|-------------------------|---------------------|
| ☐                             | ☐                                             | ☐                                    | ☐                                     | ☐                        | ☐                      | ☐                     | ☐                      | 6 weeks             |

**Engineer-To-Order (ETO)**

| Filter Elements 100% Tested | 100% Visual Inspection and Batch Record Review | Biocompatibility USP 87 or 88 Class VI | TSE|BSE EMA/410/01 & Reach | Pre-Qualified Connections | Extractables Profile | Assurance of Supply (AoS) ** | ASTM Transport Validation | Approx. Lead Time |
|-------------------------------|-----------------------------------------------|---------------------------------------|----------------------------------------|--------------------------|-------------------------|-----------------------|-------------------------|---------------------|
| ☐                             | ☐                                             | ☐                                    | ☐                                     | ☐                        | ☐                      | ☐                     | ☐                      | -                   |

**Yes** | **Case by case** | - On request | **Best AoS with Sartorius Components**
Filter and Sensor Transfer Sets

Filter and Sensor Transfer Sets are pre-assembled, pre-sterilized and fully pre-qualified ready to use filtration units for connection to single-use processing solutions. Transfer Sets consist of filters or pressure/flow sensors pre-assembled with tubing and connectors for immediate connection to single use or hybrid stainless steel systems.

Important Considerations for Process Optimization with Single-Use Transfer Sets

Verification of the Right Components
- Which component to use?
  Ask for a demo!

Implementation
- How to integrate your transfer set
- How to control your parameters
- Extractables | Leachables

Routine Operation
- Assurance of supply
- Lead times
- Integrity testing
- Calibration

Easy Integration
Pre-sterilized Filter and Sensor Transfer Sets allow an easy integration of Sartorius filters and pressure or flow measurement in a single-use set-up.

A secure connection of the Transfer Set can be carried out in the following ways:
- Sterile connectors, such as Opta®, AseptiQuik® and others
- Connection to stainless steel equipment using Steam-Thru® Connectors
- Aseptic connection (under laminar flow) using a Tri-Clamp or MPX & MPC Quick Coupler connectors
- Sterile welding of TPE Tubing (C-Flex®) using the Biowelder TC®

Sterile Transfer Sets are intended for single-use. Additional multi-use components like the pressure transmitter and the clamp-on for flow pipes can be connected to any control devices.

Complete Process Control
Both sensor systems can be connected to a controlling unit, e.g. programmable logic control or local control platforms. By combining the sterile sensor Transfer Sets with Sartorius sterile Filter Transfer Sets, you can monitor for example the pressure upstream of the filter and enable immediate shut-off of the pumps in the event of critical pressure increase.

Flexibility and Ease of Use
Whether designing a new single-use process facility or integrating disposable technology step-by-step to your existing equipment, sterile Filter and Sensor Transfer Sets provide:
- Various tubing types & lengths
- Broad choice of connectors
- Ready to use solutions

Safety
- The filter elements are 100% integrity tested
- The sensor pipes are 100% tested during manufacturing (leak, offset, particles)
- 100% visual inspection and batch record review
- All connections are pre-qualified according to Sartorius Stedim Biotech quality standards

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation. Steam-Thru® is a registered trademark of Colder Products Company. AseptiQuik® is a registered trademark of Colder Products Company.
Unprecedented Performance and Assurance of Supply

**Sterile Filter and Sensor Transfer Sets for All Process Steps**
Building on more than 20 years of experience in designing single-use solutions, we have established solutions for every media, buffer, harvest & downstream intermediates, drug substance and drug product process step.

The performance and assurance of supply of Sartorius Transfer Sets are based on the complete control of our manufacturing process for filters, sensors and the resins and extrusion of Tuflux® SIL tubes. Other fluid-contact components are secured by strategic partnerships, long term contracts and quality agreements and are available off-the-shelf to provide best delivery reliability.

**Media**
Solutions for media storage, shipping and feeding of bioreactors

**Buffer**
Solutions for storage and shipping of buffers used for purification or final formulation

**Cell Harvest & Downstream Intermediates**
Solutions for harvesting cell cultures and for handling all the process intermediates before the last cross-flow step

**Drug Substance**
Solutions for storage and shipping of drug substance post virus filtration after the last cross-flow step

**Drug Product**
Solutions for sterile filtration, hold and transfer of drug products

Read more in our Filter Overview Brochure
Pre-Designed Solutions: Standard Filter Transfer Sets

Connectors
- Opta® SFT enables sterile connections to other single-use systems
- CPC Quick Couplers (MPX) are used for either sanitary connection or aseptic connection under ISO5 laminar air flow

Filters
- Sartopore® Platinum 0.45 | 0.2 μm
- Sartopore® 2 0.45 | 0.2 μm
- Sartopore® 2 XLG 0.8 | 0.2 μm
- Sartopore® 2 XLM 0.2 | 0.1 μm

For these PES (polyethersulfone) membrane filters a broad range of sizes | filtration areas are available.

Tubing Materials
C-Flex® 374
Specifically designed for welding connections and sealing disconnections, Thermoplastic Elastomer Tubing is the ideal choice.
## Pre-Designed Solutions: Standard Filter Transfer Sets

### The Fast Solution
Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)

### Overview

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Filter</th>
<th>Tubing &amp; Outlet Connector</th>
<th>Part Number</th>
<th>Lot size</th>
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### Filter Type

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C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
# Pre-Designed Solutions: Standard Filter Transfer Sets

## Overview

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<thead>
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<th>Filter Type</th>
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<th>Tubing &amp; Outlet Connector</th>
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<th>Lot size</th>
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The Fast Solution
Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Configure-To-Order Filter Transfer Sets

Connectors
- Opta® SFT, AseptiQuik® and Kleenpak™ enable sterile connections to other single-use systems
- Tri-Clamp 1½” and ¾” sanitary flanges are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- CPC Quick Couplers are used for either sanitary connection or aseptic connection under a laminar air flow to single-use systems
- Stream-Thru® (STCII) valve allows for steaming and sterile transfer to stainless steel systems

Filters
The complete Sartorius filter range is available in a configurable transfer set. Pre-filters, sterile filters, virus filters and air filters.

Sensors
Single-use BioPAT® Pressure and Flow Sensors are also available in CTO Transfer Sets (see page 18).

Tubing Materials
Tuflux® SIL
Platinum cured Silicone Si(Pt)

C-Flex® 374
Thermoplastic Elastomer TPE

Pharma-50 & Pharma-80
Platinum cured Silicone

Advanced Pump Tubing (APT)
Platinum cured Silicone (for peristaltic pump applications)

Sani-Tech® STHT®-R
Reinforced tubing for virus filter applications

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Steam-Thru® is a registered trademark of Colder Products Company. Kleenpak™ is a trademark of Pall Corporation. AseptiQuik® is a registered trademark of Colder Products Company.
# Configure-To-Order Filter Transfer Sets

## The Flexible Solution
Configure-To-Order (CTO) Engineer-To-Order (ETO)

## Filter Options

<table>
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<tr>
<th>Filter</th>
<th>Pore Size(s) [µm]</th>
<th>Retention Rate</th>
<th>Filter</th>
<th>Membrane Material</th>
<th>Sterilization Method</th>
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Configure-To-Order Filter Transfer Sets, Gamma

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options:

- Configure-To-Order (CTO)
- Engineer-To-Order (ETO)
- Maxicaps® MR
- Pre-Designed Solutions (PDS)

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Sartorius Filter
BioPAT® Sensors

Sartorius Filter
Point of Use
Pumps

Configurables
Filter Transfer Sets

Pumps

Sartorius Filters
Point of Use

BioPAT® Sensors

Filter & Sensor Transfer Sets

Configuration

Connector & Tubing Options

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Sealing & Welding
C-Flex® tube for sterile weld with Biowelder® TC

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Kleenpak™ is a trademark of Pall Corporation.
AseptiQuik® is a registered trademark of Colder Products Company.
# The Flexible Solution

Configure-to-Order Filter and Sensor Transfer Sets with a broad range of tubing and connector options:

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<thead>
<tr>
<th>Configuration</th>
<th>Tube type</th>
<th>Connectors</th>
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<tbody>
<tr>
<td>Sartorius Filter</td>
<td>Tuflux® silicone</td>
<td>Opta® SFT</td>
</tr>
<tr>
<td>BioPAT® Sensors</td>
<td>Pharma-50</td>
<td>Tri-Clamp 1½”</td>
</tr>
</tbody>
</table>

## Connector & Tubing Options

<table>
<thead>
<tr>
<th>Filter size</th>
<th>Connector Type</th>
<th>Tubing Type</th>
<th>Tubing Length Inlet [mm]</th>
<th>Tubing Length Outlet [mm]</th>
<th>Tubing Diameter (ID – OD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midicaps® size 7</td>
<td>Opta® SFT</td>
<td>Tuflux® silicone</td>
<td>100</td>
<td>100</td>
<td>¼” – ⅜”</td>
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<tr>
<td>Midicaps® size 8</td>
<td>Tri-Clamp 1½”</td>
<td>Pharma-50</td>
<td>300</td>
<td>300</td>
<td>½” – ⅜”</td>
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<tr>
<td>Midicaps® size 9</td>
<td>Tri-Clamp ¾”</td>
<td>Pharma-80</td>
<td></td>
<td></td>
<td>½” – ⅜”</td>
</tr>
<tr>
<td>Midicaps® size 0</td>
<td>AseptiQuik® G</td>
<td>Sani-Tech® STHT® -R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxicaps® Size 10”</td>
<td>Quick Coupler MPC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxicaps® Size 20”</td>
<td>Quick Coupler MPX</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxicaps® Size 30”</td>
<td>Stream-Thru® (STCII)</td>
<td></td>
<td></td>
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</tbody>
</table>

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation. Steam-Thru® is a registered trademark of Colder Products Company. Kleenpak™ is a trademark of Pall Corporation. AseptiQuik® is a registered trademark of Colder Products Company.
## Configure-To-Order Filter Transfer Sets, Closed Design, Autoclave

### The Flexible Solution
Configure-to-Order Filter and Sensor Transfer Sets with a broad range of tubing and connector options:

- Configure-To-Order (CTO)
- Engineer-To-Order (ETO)
- Maxicaps® MR

### Connector & Tubing Options

<table>
<thead>
<tr>
<th>Filter size</th>
<th>Connector</th>
<th>Tubing Type</th>
<th>Tubing Length Inlet [mm]</th>
<th>Tubing Length Outlet [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxicaps® Size 10”</td>
<td>Opta® SFT</td>
<td>Tuflux® Silicone</td>
<td>100</td>
<td>100</td>
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<tr>
<td>Maxicaps® Size 20”</td>
<td>Tri-Clamp 1½”</td>
<td>Pharma-50</td>
<td>250 (with T-piece)</td>
<td>250 (with T-piece)</td>
</tr>
<tr>
<td>Maxicaps® Size 30”</td>
<td>AseptiQuik® G</td>
<td>Pharma-80</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>Quick Coupler MPX</td>
<td>Sani-Tech® STHT®-R</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stream-Thru® (STCII)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Kleenpak™ HT</td>
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</tr>
<tr>
<td></td>
<td>Kleenpak™ Presto</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Inlet | Outlet Connectors
- Opta® SFT
- AseptiQuik® G
- Stream-Thru® (STCII)
- Kleenpak™ HT
- Tri-Clamp 1½” sanitary flange
- Tri-Clamp mini sanitary flange
- Quick Coupler MPX
- Kleenpak™ Presto

Optional T-piece

Inlet Valve

Outlet Valve

Inlet

Outlet

Connectors

- Opta® SFT
- Midisart® 2000
- AseptiQuik® G

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Configure-To-Order Virus Filter Transfer Sets

**The Flexible Solution**
Configureable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

**Sartorius Filter**

**BioPAT® Sensors**

**Configure-To-Order (CTO)**
Inlet | Outlet Connectors
---|---
Opta® SFT | AseptiQuik® G
AseptiQuik® G | Tri-Clamp
Tri-Clamp

**Sani-Tech® STHT® -R**

**Downstream – Virosart® HF**

- Pore Size: 20 nm nom.
- Membrane Material: Asymmetric Polyethersulfone
- Sterilization Method: Gamma

<table>
<thead>
<tr>
<th>Filter Area</th>
<th>2.4 m²</th>
<th>25.8 ft²</th>
<th>0.8 m²</th>
<th>8.6 ft²</th>
<th>0.2 m²</th>
<th>2.15 ft²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubing types</td>
<td>Sani-Tech® STHT®-R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubing diameters (ID × OD)</td>
<td>Inlet</td>
<td>½” × ¾”</td>
<td>¾” × ¾”</td>
<td>½” × ¾”</td>
<td>½” × ¾”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outlet 1</td>
<td>¼” × ⅝”</td>
<td>⅞” × ⅞”</td>
<td>¼” × ⅝”</td>
<td>¼” × ⅝”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Outlet 2</td>
<td>½” × ⅜”</td>
<td>⅞” × ⅞”</td>
<td>½” × ⅜”</td>
<td>½” × ⅜”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Venting</td>
<td>½” × ¾”</td>
<td>½” × ¾”</td>
<td>½” × ¾”</td>
<td>½” × ¾”</td>
<td></td>
</tr>
</tbody>
</table>

*T* IT Wetting Kit for Virosart® HF process modules is integrated to ensure a defined back pressure without the need for manual or automated valve control and thus optimal wetting conditions.

**Tubing lengths**
(Outlet 1 & 2 have the same tubing length; Venting line is fixed)
- 150 mm, 300 mm, 500 mm, 1,000 mm

**Connectors**
(Identical connector is used for one configuration)
- Opta® SFT
- AseptiQuik® G
- Tri-Clamp 1½”

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Configure-To-Order Virus Filter Transfer Sets

The Flexible Solution
Configure-To-Order (CTO) Engineer-To-Order (ETO)
Maxicaps® MR

Upstream – Virosart® Media
- Pore Size: 20 nm nom.
- Membrane Material:
  Asymmetric Polyethersulfone
- Sterilization Method: Gamma

<table>
<thead>
<tr>
<th>Filter Area</th>
<th>1 m²</th>
<th>10.8 ft²</th>
<th>0.3 m²</th>
<th>3.2 ft²</th>
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<tbody>
<tr>
<td>Tubing types</td>
<td>Sani-Tech® STHT®-R (reinforced)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubing diameters (ID × OD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inlet</td>
<td>½” × ¾”</td>
<td>¾” × ¾”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outlet 1</td>
<td>½” × ¾”</td>
<td>¾” × ¾”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outlet 2</td>
<td>½” × ¾”</td>
<td>¾” × ¾”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venting</td>
<td>½” × ¾”</td>
<td>¾” × ¾”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tubing lengths</td>
<td>150 mm, 300 mm, 500 mm, 1,000 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Connectors (Identical connector is used for one configuration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opta® SFT</td>
</tr>
<tr>
<td>Opta® SFT</td>
</tr>
</tbody>
</table>

Sani-Tech® STHT®-R is a registered trademark of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.
Pressure Sensor Transfer Sets

- **Sartorius Flexact®**
  - 5 pressure sensor inputs available
  - sensor is readily integrated in the process control software
  - plug-and-play fashion
  - automation, alarm function and documentation

**Sensor Read-out | Options**

**Sartorius Flexact®**
- Single-Use BioPAT® Pressure Sensor
- Multi-Use Transmitter
- Do-it-yourself connection to any control unit
- use open-ends cable as power supply and data read-out
- signal is sent as an analogue 4–20 mA signal via blue and brown cable

**Single-Use BioPAT® Pressure Sensor**
- Detect pressure increase due to filter blockage
- Process monitoring | control

**Measurement Principle:**
**Piezo-resistive pressure measurement**
- The silicone membrane of the pipe and the metal membrane of the transmitter get tightly connected through an integrated fixing mechanism (not shown)
- The pressure in the pipe bends the silicone membrane, which bends the metal membrane
- The exerted force is detected by a pressure sensor within the transmitter

**Bench-top indicator for direct read-out**
- For at-line reading and simple applications without need for automation or documentation.

**Configuration Options**

- Configure-To-Order (CTO)
- Engineer-To-Order (ETO)
- Maxicaps® MR
- Pre-Designed Solutions (PDS)

**Table of Contents**
Flow Sensor Transfer Sets

**Measurement Principle**
Two pairs of sensors are fitted in one clamp-on:
- The upstream sensor sends sound waves in the direction of flow
- The downstream sensor sends sound waves against the direction of flow
- The flow accelerates the upstream sound waves and decelerates the downstream sound waves
- The detected transit time difference between the two signals is proportional to the flow velocity

**High accuracy through optimized coupling, rigid material, straight flow path**

**Precalibrated**
The sensor is precalibrated and the measurement can start immediately

**High flexibility of tubing sizes and material**
Any tubes can be connected to the pipes, even tissue-enhanced pipes. Other clamp-ons that measure on tubes can only be calibrated for one tube type.

**Highly chemically resistant**

**ADC compatible**

**High pressure applications**
The pipe can withstand a pressure of 5 bar*. The rigid material doesn’t expand or collapse with changing pressure.

**Note:** BioPAT® Flow is the world’s only ultrasonic clamp-on flowmeter with a flow pipe.

*The maximal operating pressure of an assembly is always limited to the pressure resistance of the weakest component. CTO sets are currently limited to 2 bar.
Configure-To-Order Filter Transfer Sets

The Flexible Solution
Configure-to-Order (CTO)

Overview

<table>
<thead>
<tr>
<th>Sensor</th>
<th>Connector</th>
<th>Tubing Type</th>
<th>Tubing Length Inlet [mm]</th>
<th>Tubing Length Outlet [mm]</th>
<th>Tubing Diameter (ID – OD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioPAT® Pressure</td>
<td>Opta® SFT</td>
<td>Tuflux® Silicone</td>
<td>150</td>
<td>150</td>
<td>½” – ¾”</td>
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<tr>
<td>BioPAT® Flow</td>
<td>Plug-in</td>
<td>C-Flex®</td>
<td>300</td>
<td>300</td>
<td>½” – ¾”</td>
</tr>
<tr>
<td></td>
<td>Tri-Clamp 1–½&quot;</td>
<td>Pharma-50</td>
<td>500</td>
<td>500</td>
<td>½” – ¾”</td>
</tr>
<tr>
<td></td>
<td>Tri-Clamp ¾&quot;</td>
<td>APT</td>
<td>750</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>AseptiQuik® G</td>
<td></td>
<td>1,000</td>
<td>1,500</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quick Coupler MPC</td>
<td></td>
<td>1,500</td>
<td>2,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quick Coupler MPX</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stream-Thru® (STCII)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kleenpak™ HT</td>
<td></td>
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</tr>
</tbody>
</table>

Passed ASTM Shipping Test

BioPAT® Pressure, BioPAT® Flow, Opta® SFT, Tuflux® Silicone, C-Flex®, Pharma-50, APT, AseptiQuik® G, Maxicaps® MR, Pre-Designed Solutions (PDS), Configure-To-Order (CTO), Engineer-To-Order (ETO), Table of Contents

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Sensor Transfer Sets Implementation

**Typical Applications for Pressure Measurement**
- Use of a peristaltic pump, for example when filling a single-use bag
- Overpressure from one tank to another
- Pressure measurement in front of a filter
- Process monitoring | control

**Why to use Single-Use Sensors**
Currently often used autoclavable manometers with a T-piece bring a lot of disadvantages. Leakages, calibration and the risk of oil spilling into the filling line can be avoided by using single-use solutions.

Sartorius BioPAT® Pressure and Flow sensors are available in quickly configurable standard solutions with a pressure resistance of 2 bar, which covers most applications. Customized configurations can be designed as well. For example transfer sets with braided tubing can be designed to resist up to 4 bar.

The pressure transducer only needs calibration once a year. For the Flow Pipe clamp-on Sartorius recommends to validate the correct performance every two years.

**Recommended Installation of the BioPAT® Flow Sensors**

- **Direction of flow**
  - Correct
  - Wrong

- **Straight inlet path**
  - 10 × inner diameter for systems < 3” inner diameter
  - 15 × inner diameter for systems > 3” inner diameter

To ensure proper functionality, it is important to position the sensor such that the pipe is always filled with liquid.

**Combine Sensor and Filter Transfer Sets**
Whether you prefer sterile connectors or weldable tubing the standard PDS | CTO transfer set range offers compatible options.
Single-Use Filter Transfer Set for Final Filling

Introduction
Single-Use Filter Transfer Sets for Final Filling are an industry-first configured to order solution for filtration in final filling applications.

High standardization mitigates our customers risks while operating the system, it ensures lowest residual volume due to optimal component placing and saves up to 80% delivery time. The whole set up is PUPSIT optimized, qualified, sterile and ready to use.

Pre-designed
Fast Availability

Regulatory Compliant
PUPSIT Optimized

High Standardization
Promotes Usability and Mitigates Risks

Stainless Steel Holder
Engineered to Limit Product Loss

Full Flexibility
Various Filter Types and Sizes, Single and Redundant Filtration

ASTM transport validated blister packaging
- Excellent protection also for internal transfer
- Over pouch sealing validation
- Double bagged
- Product easily removable from blister
Filter Transfer Set Final Filling

Connectors
- Opta® SFT and AseptiQuik® enable sterile connections to other single-use systems
- TPE tube with plug for sterile weld

Filters
Various types and sizes of the complete Sartopore® filter family for gamma irradiatable filter transfer sets and Sartobran P for autoclavable filter transfer sets are available.

Sampling
Flexsafe® 2D Bag
150 ml or 250 ml with Tuflux® TPE ⅛"

Mycap® Bottle
125 ml or 250 ml with C-Flex® 374 ⅛"

Waste Bag
Flexsafe® 2D Bag
- 10 L or 20 L
- Tuflux® TPE | ⅛ x ⅛ | 1,000 mm
- Tuflux® TPE | ¼ x ⅞ | 150 mm | MPC female with sealing cap

Vent | IT line
- Sartopore® Air 0.2 µm size 4
- Sani-Tech® STHT®-R | ½” x ⅞”
- Sight glass ½” inner diameter

Central Venting
Gamma Variant:
Transparent Cap polyester
TC 1.5” x ½” x ½”

HD Variant:
TEE-Connector Polypropylene
½” x ⅛” x ½”

Tubing Materials
Tuflux® SIL | ⅛” x ⅛”
Platinum cured Silicone Si(Pt)

Tuflux® TPE | ½” x ½”
Thermoplastic Elastomer Tubing

C-Flex® 374 | ½” x ¾”
Thermoplastic Elastomer TPE

Sani Tech® STHT®-R | ½” x ⅞”
Reinforced tubing for filter integrity test area only

Read more in our Data Sheet Filter Transfer Set Final Filling

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AseptiQuik® is a registered trademark of Colder Products Company.
Configure-To-Order Filter Transfer Set Final Filling

The Final Fill Solution
Filter Transfer Set
Final Filling

Filter Options

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Pore Size</th>
<th>Filter Sizes</th>
<th>Sterilization Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sartopore® Platinum</td>
<td>0.45</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
</tr>
<tr>
<td>Sartopore® Platinum HB</td>
<td>0.45</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
</tr>
<tr>
<td>Sartopore® 2</td>
<td>0.45</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
</tr>
<tr>
<td>Sartopore® 2 XLG</td>
<td>0.8</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
</tr>
<tr>
<td>Sartopore® 2 XLI</td>
<td>0.35</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
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<tr>
<td>Sartopore® 2 XLML</td>
<td>0.2</td>
<td>0.1</td>
<td>Midicaps® Size 7, 8, 9, 0</td>
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<tr>
<td>Sartobran® P</td>
<td>0.45</td>
<td>0.2</td>
<td>Midicaps® Size 7, 8, 9</td>
</tr>
</tbody>
</table>

Configuration

Single or Redundant
Tube type
Sartorius Filter
BioPAT® Pressure
Sampling
Connector
Stainless steel Holder

Configure-To-Order (CTO) Engineer-To-Order (ETO) Maxicaps® MR
Pre-Designed Solutions (PDS)
While Pre-Designed Solutions (PDS) and Configure-To-Order (CTO) Transfer Sets offer a broad design space that covers many needs, Sartorius is aware that there are specific needs that require special single-use assemblies. The Engineer-To-Order (ETO) process enables the development of customized solutions with the support of a team of application specialists. Personal assistance in finding the right single-use solution is indispensable when it comes to critical applications.

**Speed and Flexibility for the Design and Delivery of Prototypes**
- Dedicated Project Management Team across all regions (EU, US, Asia) to deliver quote in 3 – 5 days.
- ETO prototypes assembled on dedicated lines for 4 – 5 week delivery time.
- High flexibility obtained through our extensive base of components (>1,500) and qualifications integrated into a reliable and qualified custom solution.
- For new components we provide specific qualifications & studies in line with the User Requirement Specification (URS).
Large Scale Single-Use Filtration: Maxicaps® MR

Introduction
Maxicaps® MR is a unique, pre-assembled, single-use, large-scale filtration unit that reduces connections and complexity while allowing for multiple configuration options for seamless process integration.

The novel design provides integrated fluid distribution, while using 80% less tubing and only two process connections. This decreases the risk of faulty connections by up to 90% and shortens installation, test, and dismantling time by up to 87%.

Background
Single-use filter capsules have been systematically replacing stainless steel housings and filter cartridges as a highly economical and risk-adverse choice for the biopharmaceutical industry. From capsules to complex custom assemblies, implementation of single-use filter systems reduces the time it takes for equipment setup and virtually eliminates the need for cleaning.

Conventional multi-round filter housings have now evolved into single-use Maxicaps® MR systems to meet today’s advanced requirements.

C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.
Maxicaps® MR

Overview Particle Reduction & Prefilter Options

Configuration Options

<table>
<thead>
<tr>
<th>Filter</th>
<th>Retention Rate</th>
<th>Pore Size</th>
<th>Material</th>
<th>Delivery Condition</th>
<th>Number of 30’ Cartridges</th>
<th>Filtration Area (Min.)</th>
<th>Filtration Area (Max.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sartoguard PES</td>
<td>0.1 µm</td>
<td>0.2 µm</td>
<td>Polytetrafluoroethylene (PTFE)</td>
<td>Sterile</td>
<td>2–9</td>
<td>4.8 m²</td>
<td>51.6 ft²</td>
</tr>
<tr>
<td>Sartoguard GF</td>
<td>0.1 µm</td>
<td>0.2 µm</td>
<td>Polytetrafluoroethylene (PTFE)</td>
<td>Non-Sterile</td>
<td>2–9</td>
<td>2.7 m²</td>
<td>29 ft²</td>
</tr>
<tr>
<td>Sartopure® GF Plus</td>
<td>0.65 µm</td>
<td>1.2 µm</td>
<td>Glass Fiber</td>
<td>Non-Sterile</td>
<td>2–9</td>
<td>2.4 m²</td>
<td>25.8 ft²</td>
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<tr>
<td>Sartopure® PP3</td>
<td>0.45 µm</td>
<td>0.65 µm</td>
<td>1.2 µm</td>
<td>3 µm</td>
<td>5 µm</td>
<td>8 µm</td>
<td>20 µm</td>
</tr>
<tr>
<td>Sartoclean® CA</td>
<td>0.65 µm</td>
<td>0.8 µm</td>
<td>Cellulose Acetate</td>
<td>Sanitary</td>
<td>2–9</td>
<td>3.6 m²</td>
<td>38.8 ft²</td>
</tr>
<tr>
<td>Sartoclean® GF</td>
<td>0.65 µm</td>
<td>0.8 µm</td>
<td>Cellulose Acetate</td>
<td>Sanitary</td>
<td>2–9</td>
<td>2.82 m²</td>
<td>30.6 ft²</td>
</tr>
</tbody>
</table>

Venting

- Basic
- Advanced

Inlet | Outlet Tubing
- Tuflux® SIL | 750 mm
- Sani-Tech® STHT-R® | 750 mm
- Pharma-50 | 750 mm
- Tuflux® TPE | 1,500 mm
- C-Flex® 374 | 1,500 mm

Inlet | Outlet Connectors
- AseptiQuik® G
- AseptiQuik® L
- Opta® SFT Female
- Opta® SFT Male
- Presto HB
- 1.5” Sanitary Clamp
- Plug for TPE tubing

All Maxicaps® MR with gamma stable filter are delivered sterile. Non-gamma stable filters are delivered in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and hub sets finally assemblies in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

Passed ASTM Shipping Test

Read more in our Data Sheet Maxicaps® MR
Maxicaps® MR
Overview Sterilizing Grade Filter Options

Configuration Options

<table>
<thead>
<tr>
<th>Filter</th>
<th>Pore Size</th>
<th>Material</th>
<th>Delivery Condition</th>
<th>Number of 30&quot; Cartridges</th>
<th>Filtration Area (Min.)</th>
<th>Filtration Area (Max.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sartopore® Platinum</td>
<td>0.2 µm</td>
<td>Modified Polyethersulfone</td>
<td>Sterile</td>
<td>2 – 9</td>
<td>6 m²</td>
<td>64.6 ft²</td>
</tr>
<tr>
<td>Sartopore® 2</td>
<td>0.2 µm</td>
<td>0.45 µm</td>
<td>Polyethersulfone</td>
<td>Sterile</td>
<td>2 – 9</td>
<td>3.6 m²</td>
</tr>
<tr>
<td>Sartopore® 2 XLG</td>
<td>0.2 µm</td>
<td>Polyethersulfone</td>
<td>Sterile</td>
<td>2 – 9</td>
<td>4.8 m²</td>
<td>51.6 ft²</td>
</tr>
<tr>
<td>Sartopore® 2 XLI</td>
<td>0.2 µm</td>
<td>Polyethersulfone</td>
<td>Sterile</td>
<td>2 – 9</td>
<td>4.8 m²</td>
<td>51.6 ft²</td>
</tr>
<tr>
<td>Sartopore® 2 XLM</td>
<td>0.1 µm</td>
<td>Polyethersulfone</td>
<td>Sterile</td>
<td>2 – 9</td>
<td>4.8 m²</td>
<td>51.6 ft²</td>
</tr>
<tr>
<td>Sartobran® P</td>
<td>0.2 µm</td>
<td>0.45 µm</td>
<td>Cellulose Acetate</td>
<td>Sanitary</td>
<td>2 – 9</td>
<td>3.6 m²</td>
</tr>
</tbody>
</table>

Venting
- Basic
- Advanced

Inlet | Outlet Tubing
- Tuflux® SIL | 750 mm
- Sani-Tech® STHT-R® | 750 mm
- Pharma-50 | 750 mm
- Tuflux® TPE | 1,500 mm
- C-Flex® 374 | 1,500 mm

Inlet | Outlet Connectors
- AseptiQuik® G
- AseptiQuik® L
- Opta® SFT Female
- Opta® SFT Male
- Presto HB
- 1.5" Sanitary Clamp
- Plug for TPE tubing

All Maxicaps® MR with gamma stable filter are delivered sterile. Non-gamma stable filters are delivered in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and tub sets finally assembled in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

Read more in our Data Sheet Maxicaps® MR

Passed ASTM Shipping Test
Maxicaps® MR Virosart® Max

Overview Virus Pre-Filter Options

<table>
<thead>
<tr>
<th>Configuration Options</th>
<th>Filter</th>
<th>Pore Size</th>
<th>Material</th>
<th>Delivery Condition</th>
<th>Number of 30” Cartridges</th>
<th>Filtration Area (Min.)</th>
<th>Filtration Area (Max.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maxicaps® MR Virosart® Max</strong></td>
<td>0.1 µm</td>
<td>Polyamide</td>
<td>Sanitary</td>
<td>2 – 9</td>
<td>4.2 m²</td>
<td>18.2 m²</td>
<td></td>
</tr>
</tbody>
</table>

### Inlet | Outlet Tubing
---
Tuflux® SIL | 750 mm
Sani-Tech® STHT-R | 750 mm
Pharma-50 | 750 mm
Tuflux® TPE | 1,500 mm
C-Flex® 374 | 1,500 mm

### Inlet | Outlet Connectors
---
AseptiQuik® G
AseptiQuik® L
Opta® SFT Female
Opta® SFT Male
Presto HB
1.5” Sanitary Clamp
Plug for TPE tubing

Maxicaps® MR Virosart® Max is available only in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and tub sets finally assembled in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

Read more in our Data Sheet Maxicaps® MR

Passed ASTM Shipping Test
Maxicaps® MR Virosart® Media and HF

Overview Virusfilter Options

Maxicaps® MR Virosart® Media and HF is available in various pre-defined configurations.

<table>
<thead>
<tr>
<th>Filter</th>
<th>Pore Size</th>
<th>Material</th>
<th>Delivery Condition</th>
<th>Number of Process Modules</th>
<th>Filtration Area (Min.)</th>
<th>Filtration Area (Max.)</th>
<th>Inlet Tubing</th>
<th>Inlet Connectors</th>
<th>Outlet Tubing</th>
<th>Outlet Connectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virosart® Media</td>
<td>20 nm</td>
<td>Polyethersulfone Surface modified</td>
<td>Gamma Irradiated</td>
<td>3 or 6</td>
<td>3 m²</td>
<td>32.3 ft²</td>
<td>6 m²</td>
<td>64.6 ft²</td>
<td>Reinforced silicon tubing</td>
<td>2 × AseptiQuik® G on Tri-Clamp 1½”</td>
</tr>
<tr>
<td>Virosart® HF</td>
<td>20 nm</td>
<td>Polyethersulfone Surface modified</td>
<td>Gamma Irradiated</td>
<td>2 – 6</td>
<td>4.8 m²</td>
<td>51.7 ft²</td>
<td>14.4 m²</td>
<td>155 ft²</td>
<td>Reinforced silicon tubing</td>
<td>2 × AseptiQuik® G on Tri-Clamp 1½”</td>
</tr>
</tbody>
</table>

AseptiQuik® is a registered trademark of Colder Products Company.
Validation and Quality Assurance

Component Quality, Change Control and Business Continuity

Critical fluid-contact components used for Transfer Sets are secured by long term contracts and quality agreements to offer the best assurance of supply. Many designs are also available off-the-shelf to offer the best delivery reliability.

Components are selected to meet the most stringent quality requirements and all engagements with tubings are extensively qualified to ensure consistent robustness.

Our supply contracts ensure at least a 2-year change notification thus providing robust change control and business continuity.

Material Qualification

Filter and Sensor Transfer Set components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers.

Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

Design Qualification

Component designs are selected to maximize tubing engagement tensile strength and tightness. All engagements with tubings are qualified for at least 2 years shelf life*. Test samples are visually inspected for absence of defect and tested for leak and traction.

Material Qualification

Filter and Sensor Transfer Set components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers.

Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

Design Qualification

Component designs are selected to maximize tubing engagement tensile strength and tightness. All engagements with tubings are qualified for at least 2 years shelf life*. Test samples are visually inspected for absence of defect and tested for leak and traction.

* Virus Filter Transfer Sets have 1 year shelf life

Filter and Sensor Transfer Sets

<table>
<thead>
<tr>
<th>Components</th>
<th>Biological compatibility (USP Class VI)</th>
<th>Endotoxin Sub visible particles bioburden</th>
<th>TSE</th>
<th>BSE EMA/410/01 &amp; REACH</th>
<th>Change Control Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuflux® tubes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months</td>
</tr>
<tr>
<td>Opta® sterile connectors</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months</td>
</tr>
<tr>
<td>Fittings</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months</td>
</tr>
<tr>
<td>Connectors</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months</td>
</tr>
<tr>
<td>Filters</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months**</td>
</tr>
<tr>
<td>Sensor Pipes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>24 months**</td>
</tr>
</tbody>
</table>

** Minor changes might have a shorter notification time. Changes will be evaluated according to the Sartorius Change Matrix.

Our core expertise in plastics and polymers enables the selection of the cleanest and most inert materials to minimize chemical interactions with biopharmaceutical fluids to provide consistent cell growth.
Validation and Quality Assurance

Transfer Sets are qualified using extensive biological, chemical, physical, extractable and cell growth testing to provide reliable data for validation purposes applicable to a wide range of process conditions.

**Sartorius Stedim Biotech Quality**

Systems for single-use products follow applicable ISO 9001 and FDA regulations. Because single-use systems replace traditional stainless steel equipment, suppliers own a more important part of the drug manufacturing process. Design, manufacture, quality control and sterilization of Filter and Sensor Transfer Sets are conducted under conditions that mirror biopharmaceutical operations like requirements to ensure they are supplied clean, pure, endotoxin free and sterile.

**Filter and Sensor Transfer Sets**

are qualified and routinely controlled to provide consistent performance.

Additional tubing materials, components and pressure ratings are available for customized assemblies upon request.

**Biocompatibility and Chemical Compatibility**

- ISO 10993: Biological reactivity tests, in Vitro
  Not available for all components see SD152370
- USP<87>: Biological reactivity tests, in Vitro
- USP<88>: Biological reactivity tests, in Vivo
- Internal standardized methods for cell growth compatibility evaluation

**Purity, Extractable & Potential Leachable**

- Extractable data based on knowledge and control of resins and film manufacturing process
- TSE/BSE: EP 5.2.8

**Cleanliness, Particles**

- USP<788> and EP 2.9.19: Particulate Matter in Injections
  Endotoxin
- USP<85> and EP 2.6.14: Bacterial endotoxins Sterility
- ISO 11737 Sterilization of medical devices – Microbiological methods: Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices
- ISO 17665 Steam Sterilization
- ISO 14644: Cleanroom environmental controls

**Quality Assurance Certificate (PDS & CTO)**

<table>
<thead>
<tr>
<th>Statement</th>
<th>Monitoring</th>
<th>Batch Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biosafety</strong></td>
<td>Bacterial Endotoxins</td>
<td><strong>Bacterial Retention</strong></td>
</tr>
<tr>
<td>USP 87 or 88 Class VI</td>
<td>USP 85 and EP 2.6.14.</td>
<td>Each 0.2 and 0.1 µm membrane lot</td>
</tr>
<tr>
<td>TSE-BSE</td>
<td>Bioburden</td>
<td>membrane lot according to ASTM 838</td>
</tr>
<tr>
<td>EMA/410/01</td>
<td><strong>Particulate Matter</strong></td>
<td><strong>Virus Retention</strong></td>
</tr>
<tr>
<td></td>
<td>USP “Large Volume Injections for Single Dose Infusion”</td>
<td>Each 20 nm membrane lot is tested for PP7 retention</td>
</tr>
<tr>
<td></td>
<td><strong>Integrity Test</strong></td>
<td><strong>Visual Inspection</strong></td>
</tr>
<tr>
<td></td>
<td>Each integrity testable membrane filter element was tested by means of diffusion and bubble point testing</td>
<td>100% of the products</td>
</tr>
<tr>
<td></td>
<td><strong>Visual Inspection</strong></td>
<td><strong>Product Conformity</strong></td>
</tr>
<tr>
<td></td>
<td>100% of the products</td>
<td>Technical drawing and batch record review</td>
</tr>
<tr>
<td></td>
<td><strong>Sterilization</strong></td>
<td><strong>Sterilization</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sartorius Extractables & Leachables Approach

Sartorius developed a new extractables matrix based on over 20 years of experience, know-how and results of recent internal studies and consideration of BPOG, USP and ASTM. It provides worst case and consistent extractables data for Sartorius components and products.

For single-use Transfer Sets Sartorius is following a component approach.

Four levels of support are provided depending on the criticality of their intended use in the manufacturing process:

1. Extractables guides per major component or product family.
2. Extractables reports: Data extrapolated from the component tested to a multi-component assembly (data selected from Opta® connector, tubing and filter extractables guide).
3. Process related extractables reports: Data extrapolated from the component tested to a multi-component assembly and related to specific end user process conditions (surface | volume ratio, contacting fluid and contact conditions based on the application).
4. Leachables studies: Extraction and study conditions with specific pharmaceutical solutions | product and process conditions.

The extensive data provided in our Validation Guides and Extractables Guides builds a comprehensive basis for the risk assessment of your respective process and product.

We work in partnership with you to develop the appropriate Extractables & Leachables approach – risk-based and adapted to your specific production environment.

Legal requirements, rapid time-to-market, high cost efficiency:
We understand the daily challenges in the biopharmaceutical industry and know what is important in your business.
Implementation and Validation Services

**Application Support**
Our expert Application Specialists provide global support for:

- Single-use process URS definitions and application development
- Process design with standard and custom solutions
- Filter selection and sizing optimization study
- SOP development, process validation and operator training
- Technology transfer and process optimization

**Instrument Services**
- Installation start up, FAT, IQ & OQ, calibration and maintenance

**Validation Services**
Our global validation services network offers consultancy service as well as product and process specific validation studies including a comprehensive test portfolio:

- Risk assessment support
- Grouping | Bracketing support
- Microbiological tests
- Chemical | Physical tests
- Extractables | Leachables tests

Find out more
For more information, please visit www.sartorius.com