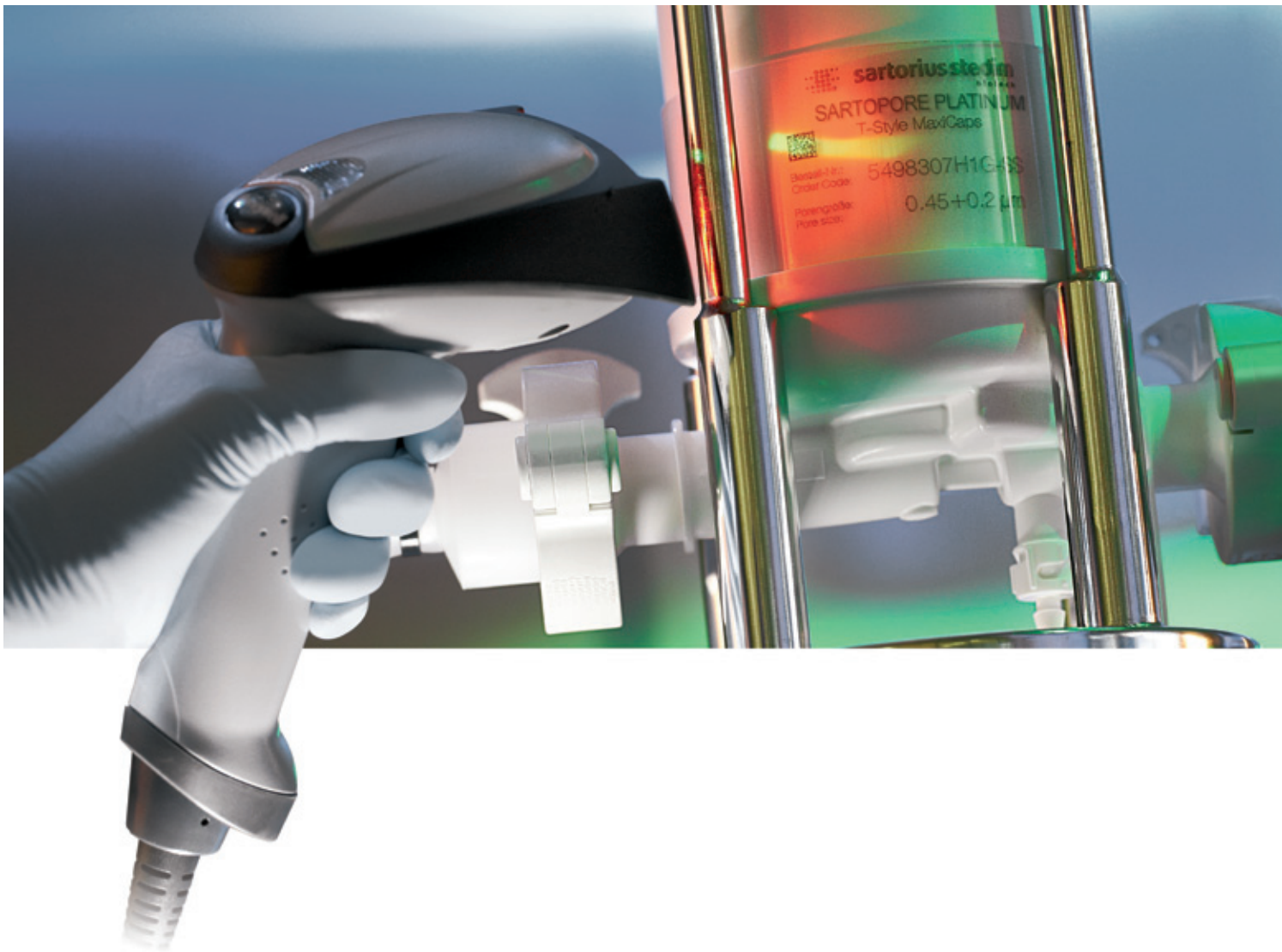




sartorius stedim
biotech

Filtration Technology Overview for the Biopharmaceutical Industry




turning science **into solutions**

A Profile of Sartorius Stedim Biotech

Sartorius Stedim Biotech is a leading provider of cutting-edge equipment and services for the development, quality assurance and production processes of the biopharmaceutical industry. Its integrated solutions covering fermentation, filtration, purification, fluid management and lab technologies are supporting the biopharmaceutical industry around the world to develop and produce drugs safely, timely and economically. Sartorius Stedim Biotech focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Strongly rooted in the scientific community and closely allied with customers and technology partners, the company is dedicated to its philosophy of 'turning science into solutions'.

Headquartered in Aubagne, France, Sartorius Stedim Biotech is listed on the Eurolist of Euronext Paris. With its own manufacturing and R&D sites in Europe, North America and Asia and a global network of sales companies, Sartorius Stedim Biotech enjoys a worldwide presence. Its key manufacturing and R&D site is in Germany.

The logo for Sartorius Stedim Biotech, featuring a stylized grid of dots to the left of the company name. The name "sartorius stedim" is in a bold, lowercase sans-serif font, with "biotech" in a smaller, lowercase sans-serif font below it.

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Filtration Technology

Sartorius Stedim Biotech's filter products are especially designed developed and manufactured to match the application requirements of the biopharmaceutical industry ranging from R&D to pilot scale production and to commercial scale manufacturing. Backed up by decades of experience we guarantee consistent product quality, reliable supply, easy scale-up and multiple product configurations and materials for flexible integration of our filtration solutions into biopharmaceutical manufacturing processes.

Applications

Cartridges, Mini Cartridges, MidiCaps® and MaxiCaps® are available with a multitude of different membrane and filter active fleece materials making them ideally suited for a broad range of applications in biopharmaceutical manufacturing across the complete process chain. These applications include:

- Sterilizing Grade Filtration
- Mycoplasma Retentive Filtration
- Bioburden Reduction
- Prefiltration
- Clarification
- Air & Gasfiltration

Unique Labeling

All filter products of Sartorius Stedim Biotech feature a comprehensive and easy to read out labeling on the housing of the filter capsules or on the top-adaptor of filter cartridges. This labeling typically includes:

- Filter Type
- Order Code | Lot Number
- Pore Size or Retention Rating
- Operating Parameters
- Flow Direction Indication (only for MidiCaps® and MaxiCaps®)
- 2-dimensional barcode incorporating the identical information

The labeling allows secure identification of each filter unit and assures traceability of the filters across the whole process. The 2-d barcode labeling allows together with the integrity testing unit Sartocheck® 4 Plus

the automatic data transfer of the filter element into the pre-determined fields of the integrity tester while programming an integrity test. As a result operator errors and mishandling of filters can be avoided, thus improving filter handling and overall security of the manufacturing process significantly.

Certified Quality

All Sartorius Stedim Biotech filter products are manufactured according to an ISO 9001:2000 certified Quality Management System. Our manufacturing facilities operate in conformance with cGMP requirements in addition to the ISO standard. Sartorius Stedim Biotech's quality philosophy ensures that our customers receive products and services that meet the strictest quality requirements and assure reliable product performance.

Documentation

The entire range of our filter products is supplied with quality assurance certificates for compliance with regulatory requirements. Comprehensive product specific Validation Guides and Extractable Guides are available for all Sartorius Stedim Biotech filter products to support your process validation efforts.

Process Validation

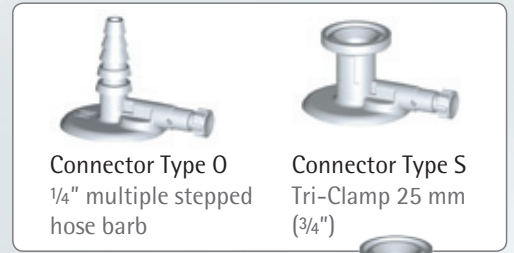
Sartorius Stedim Biotech offers a wide range of validation support services to qualify the use of our filter products for your processes. The Sartorius Stedim Biotech Validation Service has a proven track record in assisting customers in validating their products and achieving regulatory approval.



Unparalleled Flexibility

Independently whether you run your filtration process on re-usable stainless steel equipment or a fully single use manufacturing process, Sartorius Stedim Biotech provides you with the right choice of filter designs and configurations for each process requirement. Standard filter cartridges and Mini Cartridges are available in different sizes and with multiple adapter geometries to fit into stainless steel housings. MaxiCaps® in T-Style or "in-line" format and MidiCaps® feature a broad variety of special adapter combinations and filter sizes to allow for a flexible integration into single use filtration systems and to adapt to changing process volumes.

Sartorius Stedim Biotech's filter products for liquids and gases are available starting with SartoScale devices with 17 cm² filtration area up to 3 m² filtration area in Sartopore® Platinum 30" cartridges and MaxiCaps® allowing for reliable Scale-up with consistent materials and design parameters from R&D to commercial manufacturing.



Size 4 Capsules



T-Style MaxiCaps®



Connector Type S
Tri-Clamp 50 mm (1 1/2")



Connector Type O
1/2" single stepped hose barb



Connector Type Y
1" single stepped hose barb



Adapter 15
Bayonet adapter with o-ring



Adapter 18
Plug adapter with double o-ring



Mini Cartridges



MidiCaps®



Connector Type S
Tri-Clamp 50 mm
(1 1/2")



Connector Type O
1/2" single stepped
hose barb



Connector Type F
Tri-Clamp 25 mm
(3/4")



Connector Type H
1/4" multiple stepped
hose barb



Connector Type S
Tri-Clamp 50 mm
(1 1/2")



Connector Type O
1/2" single stepped
hose barb



Connector Type F
Tri-Clamp 25 mm
(3/4")



MaxiCaps®



SartoScale



Connector Type F
Tri-Clamp 25 mm (1/2")

Cartridges



Adapter 21
Double open end
with flat gaskets



Adapter 25
2 Flange Bayonet adapter
with 226 double o-ring



Adapter 27
Bayonet adapter with
222 double o-ring



Adapter 28
3 Flange Bayonet adapter
with 222 double o-ring



Application Matrix

This matrix provides a guideline for selection of the right filter in a given application backed up by decades of experience in the biopharmaceutical industry. However, it is recommended carrying out small scale filtration trials to identify the optimal filter combination based on actual process conditions.

Process	Application	Prefilters					Bioburden Reduction		
		Sartoclean®		Sartopure®		Sartofine	Sartoguard		
		GF	CA	PP2	GF Plus	PP	PES	GF	NF
Biotech									
mAb, rec. Proteine Vaccines	Media Preparation				●		●	●	●
	Cell Culture Fermentation pH adjustment			●					
	Cell Removal Clarification	●	●		●	●		●	
	Buffer Preparation			●		●	●		
	Downstream Intermediates (Protection of Columns, Crossflow)	●	●		●		●	●	●
	Prefiltration prior to virus filtration						●	●	●
	Form & Fill			●					
Viral Vaccines Cell Culture	Media Preparation				●		●	●	●
	Cell Culture Fermentation pH adjustment			●					
	Cell Removal Clarification	●	●		●	●		●	
	Buffer Preparation			●		●	●		
	Downstream Intermediates (Protection of Columns, Crossflow)	●	●	●	●		●	●	●
	Form & Fill		●	●					
Pharma									
Ophthalmics	Form & Fill			●	●				
SVP LVP	Form & Fill			●		●			
API	Form & Fill			●		●			
Blood & Plasma									
Albumin Globulines	Intermediate Process Filtration (Protection of Columns, Crossflow)	●	●	●	●	●	●	●	●
	Prefiltration prior to virus filtration							●	●
	Form & Fill			●					
Clotting Factors	Intermediate Process Filtration (Protection of Columns, Crossflow)	●	●	●		●			
	Prefiltration prior to virus filtration								
	Form & Fill			●					
Other									
	Water			●					
	Oily formulations			●		●			
	Solvents			●		●			
	Venting Gas Filtration			●					

● recommended | ● alternatively recommended

Sterile Liquid Filters

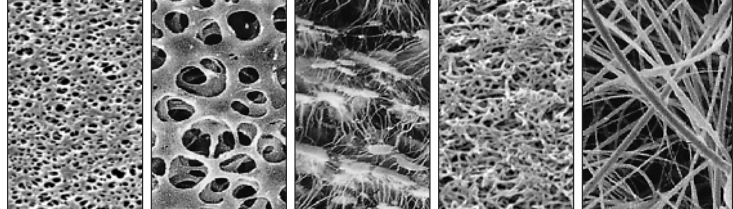
Mycoplasma Retentive Filters

Air | Gas Filtration

Sartopore® Platinum**	Sartopore® 2			Sartobran® P	Sartolon®	Sartopore® 2	Sartopure®	Sartofluor®
0.2 µm	HF	XLG	XLI	0.2 µm		XLM	GA	GA LG
●		●	●	●		●		
●								
●		●		●				
●	●			●				
●		●	●	●				
						●		
●		●	●	●		●		
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					●			●
					●			●
							●	●*

* sterile applications | ** alternatively Sartopore® 2

Membrane Filters

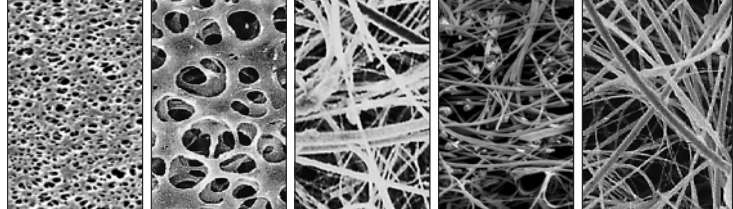


	Cartridge Construction	Polyether-sulfone	Cellulose Acetate	PTFE	Nylon	Poly-propylene
Sartopore® Platinum Sterilizing Grade pharmaceutical filter with TwinPleat® Technology and permanently hydrophilic membrane surface modification for optimal total throughput, low binding and low flush volumes for secure and reliable integrity testing.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartopore® 2 Sterilizing Grade and Mycoplasma retentive pharmaceutical filter with high total throughput and flow rate performance in a broad range of applications with broad chemical compatibility.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartopore® 2 XLG Sterilizing Grade pharmaceutical filter especially developed for complex cell culture media filtration and biological process fluids with broad chemical compatibility.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartopore® 2 XLI Sterilizing Grade pharmaceutical filter especially developed for chemically defined cell culture media and classical pharmaceuticals with broad chemical compatibility.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartopore® 2 XLM Mycoplasma retentive filter especially developed for secure retention of Mycoplasma and unusually small microorganisms in cell culture media and biological and pharmaceutical fluid streams.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartopore® 2 HF Sterilizing Grade pharmaceutical filter especially developed for filtration of buffers and large volume parenterals with exceptionally high flow rate.	Protective Layer					●
	Final Membrane	●				
	Drainage layer					●
	Outer Cage, Core and End Caps					●
Sartobran® P Sterilizing Grade pharmaceutical filter with cellulose acetate membrane low unspecific adsorption and highest product yield for filtration of highly valuable protein and virus solutions.	Protective Layer					●
	Prefilter Membrane		●			
	Final Membrane		●			
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartolon® Sterilizing Grade pharmaceutical filter with nylon membrane with broad chemical compatibility for solvents and solvent based formulations.	Protective Layer					●
	Prefilter Membrane				●	
	Final Membrane				●	
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartofluor® GA LG Sterilizing Grade pharmaceutical filter with highly hydrophobic PTFE membrane for sterilizing grade filtration of gases and aggressive liquids.	Protective Layer					●
	Final Membrane			●		
	Drainage Layer					●
	Outer Cage, Core and End Caps					●

O-Rings Standard	Pore Size Combinations	Autoclavable	γ-irradiatable		Adapter Type Standard	Cartridges Mini	Connector Types* Maxi- & MidiCaps®
			MidiCaps®	MaxiCaps®			
Silicone (optional: EPDM or Viton)	0.45 + 0.2 μm	●	●	●	25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.8 + 0.45 μm 0.45 + 0.2 μm 0.2 + 0.1 μm	●	●	●	21, 25, 27, 28	15, 18	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.8 + 0.2 μm	●	●	●	25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.35 + 0.2 μm	●			25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.2 + 0.1 μm	●		●	25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.2 μm	●			25	–	–
Silicone (optional: EPDM or Viton)	0.65 + 0.45 μm 0.45 + 0.2 μm 0.45 + 0.1 μm	●			21, 25, 27, 28	15, 18	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.45 + 0.2 μm	●			21, 25, 27, 28	15	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.2 μm (GA) 0.1 μm (GA) 0.45 μm (LG) 0.2 μm (LG) 0.1 μm (LG)	●			25 (GA) 25, 28 (LG) 21, 27	12, 15, 18 14 (Junior)	SS 00 SO FF

* other connector combinations available on request

Prefilters



	Cartridge Construction	Polyether-sulfone	Cellulose Acetate	Glass Fiber	PES Nanofleece	Poly-propylene
Sartoguard PES Pharmaceutical Grade membrane prefilter for bioburden reduction and protection of sterilizing grade and Mycoplasma retentive filters broad chemical compatibility.	Protective Layer					●
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartoguard GF Pharmaceutical Grade membrane prefilter for bioburden reduction and protection of sterilizing grade and Mycoplasma retentive filters with adsorptive power of glass fiber fleeces for effective removal of colloids and lipids.	Protective Layer					●
	Filter Active Fleece			●		
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
Sartoguard NF Pharmaceutical Grade, gamma irradiatable membrane prefilter for bioburden reduction and protection of sterilizing grade and Mycoplasma retentive filters with innovative Nanofleece technology for enhanced flow rate and throughput.	Protective Layer					●
	Filter Active Fleece				●	
	Prefilter Membrane	●				
	Final Membrane	●				
	Drainage Layer					●
Sartoclean® CA Pharmaceutical Grade membrane prefilter with low adsorptive cellulose acetate membrane for low unspecific adsorption and highest product yield.	Protective Layer					●
	Prefilter Membrane		●			
	Final Membrane		●			
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
Sartoclean® GF Pharmaceutical Grade membrane prefilter for bioburden reduction and protection of sterilizing grade and Mycoplasma retentive filters with adsorptive power of glass fiber fleeces for effective removal of colloids and lipids.	Protective Layer					●
	Filter Active Fleece			●		
	Prefilter Membrane		●			
	Final Membrane		●			
	Drainage Layer					●
Sartopure® PP2 Pharmaceutical Grade prefilter for particle removing polypropylene depth filter.	Protective Layer					●
	Filter Active Fleece					●
	Drainage Layer					●
	Outer Cage, Core and End Caps					●
	Sartopure® GF Plus Pharmaceutical Grade adsorptive glass fiber prefilter for effective removal of colloids and liquids and outstanding total throughput performance.	Protective Layer				
Filter Active Fleece				●		
Drainage Layer						●
Outer Cage, Core and End Caps						●
Sartofine® PP Pharmaceutical Grade depth prefilter made of progressively finer Polypropylene fleeces wound around the inner core with high dirt holding capacity.	Protective Layer					●
	Filter Active Fleece					●
	Drainage Layer					●
	Outer Cage, Core and End Caps					●

O-Rings Standard	Pore Size Combinations	Autoclavable	γ-irradiatable		Adapter Type Cartridges		Connector Types* Maxi- & MiniCaps®
			MidiCaps®	MaxiCaps®	Standard	Mini	
Silicone (optional: EPDM or Viton)	0.45 + 0.1 μm 1.2 + 0.2 μm	●		●	25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.45 + 0.1 μm 0.8 + 0.2 μm	●			25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	0.45 + 0.1 μm 0.8 + 0.2 μm	●	●	●	25	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	3 + 0.8 μm (double layer) 0.8 + 0.65 μm (double layer) 0.45 μm (single layer) 0.2 μm (single layer)	●			21, 25, 27, 28	15	SS 00 SO FF
Silicone (optional: EPDM or Viton)	3 + 0.8 μm 0.8 + 0.65 μm	●			21, 25, 27, 28	15	SS 00 SO FF

**Nominal
Retention Ratings**

Silicone (optional: EPDM or Viton)	50 μm 3 μm 20 μm 1.2 μm 8 μm 0.65 μm 5 μm	●			21, 25, 27, 28	15	SS 00 SO FF
Silicone (optional: EPDM or Viton)	1.2 μm 0.65 μm	●			21, 25, 27, 28	–	SS 00 SO FF
Silicone (optional: EPDM or Viton)	40 μm 3 μm 20 μm 1 μm 10 μm 0.7 μm 5 μm 0.5 μm	●			00 (knife edge), 03, 05, 07, 08	–	–

* other connector combinations available on request

Filter Integrity Testing and Bag Testing

Filter Integrity Testing and Bag Testing | Sartorius Stedim Biotech offers a broad range of testing solutions – beginning with our stand-alone units of the Sartocheck® family for standard applications up to customized solutions like the WITHin concept and special filter management systems. There are no limits in terms of technical flexibility.

Sartocheck® 3 plus

The stand-alone integrity tester for standard applications. This unit can be used to perform all established integrity test methods. Due to its paper-based concept the requirements regarding 21 CFR part 11 are not applicable.

Sartocheck® 4 plus Filter tester

The state-of-the-art integrity tester Sartocheck® 4 plus Filter tester offers a variety of additional features: An optional barcode scanner can be used for easy and error-free data entry. Moreover, an intelligent, automatic selection of test program after scanning increases the efficacy and safety of filter integrity testing. Short test times, new safety parameters and a unique cleaning function are only some of the key characteristics. And the compliance with 21 CFR Part 11 is a matter of course.

Sartocheck® 4 plus MultiUnit concept

Up to four Filter testers and/or Bag tester MultiUnits can be connected to one Sartocheck® 4 plus Filter tester or to one Sartocheck® 4 plus Bag tester allowing independent and parallel testing of five systems. This significantly reduces the time required for testing and therefore improves the cost effectiveness.

Sartocheck® 4 plus Bag tester

The Sartocheck® 4 plus Bag tester is the ideal tool for eliminating the risk of filling a defective single use bioreactor with high valuable cell cultures. The bioreactor (e.g. STR Cultibag) is tested pre-use after installation into its holder. A unique patented fleece avoids direct contact between the plastic film of the bag and the smooth stainless steel surface of the holder. Any kind of potential masking effect is therefore eliminated and environmental heat transfer is reduced giving unrivalled test accuracy.



Filter Management Systems

WITHin Concept

The WITHin concept allows integrity testing of filters inside specific equipment like autoclaves and freeze-dryers without connecting an external integrity tester. This unique Sartorius Stedim concept integrates Sartochek® control functions as well as algorithms directly into the software platforms of the equipment manufacturer. This approach is adopted worldwide by leading manufacturers of autoclaves, freeze dryers, filling machines and bioreactors.

Filter Management System

The concept of the Filter Management System implements the in-place and off-line method which saves expensive time and eliminates the risk of integrity test failures before production runs. The filter is tested in its filter housing on a test bench and all integrity test steps can be performed automatically under sterile conditions. The sterile housing can then be installed and only the connection between the filter housing and the equipment requires to be sterilized.



Filter Cartridge Housings

There has been, and is, an increasing demand for quality filter cartridge systems for sterilizing and polishing filtration processes. An emphasis has been placed on the integrity of construction of the filter cartridges. However, the filter cartridge housing is just as an important part of any filtration system. Without a proper housing the cartridge is useless.

Even the best filter cartridge cannot do the job if enclosed in a housing that allows fluid to bypass the filter, has external leaks, are not chemically or mechanically compatible with the application. Quality gas or liquid filtration systems require both quality housings and quality filter cartridges. To meet this need, Sartorius Stedim Biotech has been producing a sanitary line of housings with focusing on quality.





Sartorius Stedim Biotech standard filter housings meet the highest requirements of the biopharmaceutical industry. Controlled production engineering is a guarantee for outstanding quality in processing and operational safety. All filter cartridge housings comply with Pressure Equipment Directive PED 97/23/EC. Our housings additionally feature GMP compliant designs and FDA/USP Class VI approved gasket materials. Meticulously processed surfaces ensure operational safety wherever sterility and cleanability are concerned. Customer-specific documents are available for every filter cartridge housing. If requested, we can supply housing designs customized to meet your specific application.

An important feature of pharmaceutical process validation is documentation. All our housings are given stringent inspections during and after manufacturing including dimensional checks, weld inspections, surface measurements and hydrostatic testing. Each housing is labeled by laser with a matching serial number on the bell and base. This serial number provides complete traceability for the Quality Control Certificate, Material Test Reports, and Weld Logs.



Services

Our capabilities are your key to success.

Source all your needs from one reliable partner for process optimization, customized validation and regulatory support, substantiated by practical training courses and instrument services. We are aware of our responsibilities toward the success of your business, and take them seriously. That's why we are rapidly deployable and globally available.

You can expect the very best in science-driven consulting service, maximum regulatory expertise by our specialists, fast turn-around, on-site support and globally valid standards from Sartorius Stedim Biotech. But don't take our word for it. We invite you to see for yourself. Count on the people who know your industry inside and out: Sartorius Stedim Biotech.

CONFIDENCE®

Our validation services:

- Validation designs
- Pre-approval inspection preparation
- Post-approval change support
- CFR 21 Part 11 | GAMP compliance
- Regulatory liaison
- Equipment qualification
- Filter | Cleaning | Process validation
- Risk assessment support
- Grouping support
- Extractables | Leachables testing for filters, fluid management systems and other polymer-based process components like tubing, gaskets, stoppers.

EXPAND®

Our training and seminar services:

- FDA risk-based approach
- Regulatory inspection
- CFR 21 Part 11 | GAMP
- Aseptic processing
- Upstream | Downstream processing
- Process validation
- Cell culture | Fermentation
- Sterilization and integrity testing
- Quality control and quality assurance

Explore your possibilities – we continue to lead and innovate in the field of services to increase the added value to the biopharmaceutical and pharmaceutical industry. Visit our website www.sartorius-stedim.com



EXTEND®

Our instrument services:

- Installation
- IQ | OQ support and documentation
- Calibration services
- Spare part sales
- Preventative maintenance
- Instrument repairs
- Technical and application support

We take our responsibilities seriously
in order to ensure your productivity.

DISCOVER®

Our audit and survey services:

- Compliance audits
- Regulatory inspection readiness
- Plant | Process surveys
- Validation surveys
- Quality system surveys
- Technical studies

INCREASE®

Our optimization services:

- Corrective actions guidance
- Process optimization and development support
- Design review and technology transfer
- Documentation and submittal optimization
- Regulatory guidance





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