Filter Housing Catalogue 1.0

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Simplifying Progress

SARTORIUS

General Information

A new performance of delivery
- Short delivery time
- Flexible options

Focused quality -
Filter cartridge housings

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 2014|68|EU and design code AD2000.
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.

General housing data	
Operation pressure	-1 bar up to +10 bar
Operation temperature	-10°C up to +150°C
Surface Inner|Outer	0.4 µm | 1.2 µm (electro-polished)
Medium group	1 (dangerous)
PED	DGRL 2014|68|EU
Design-Code	AD2000
Housing material „L“	AISI 316L (1.4404 | 1.4435)
Gasket „E“	EPDM
Documentation „Z“	„Z“ Premium Documentation Package

Each housing is delivered with the “Z” Premium Documentation Package

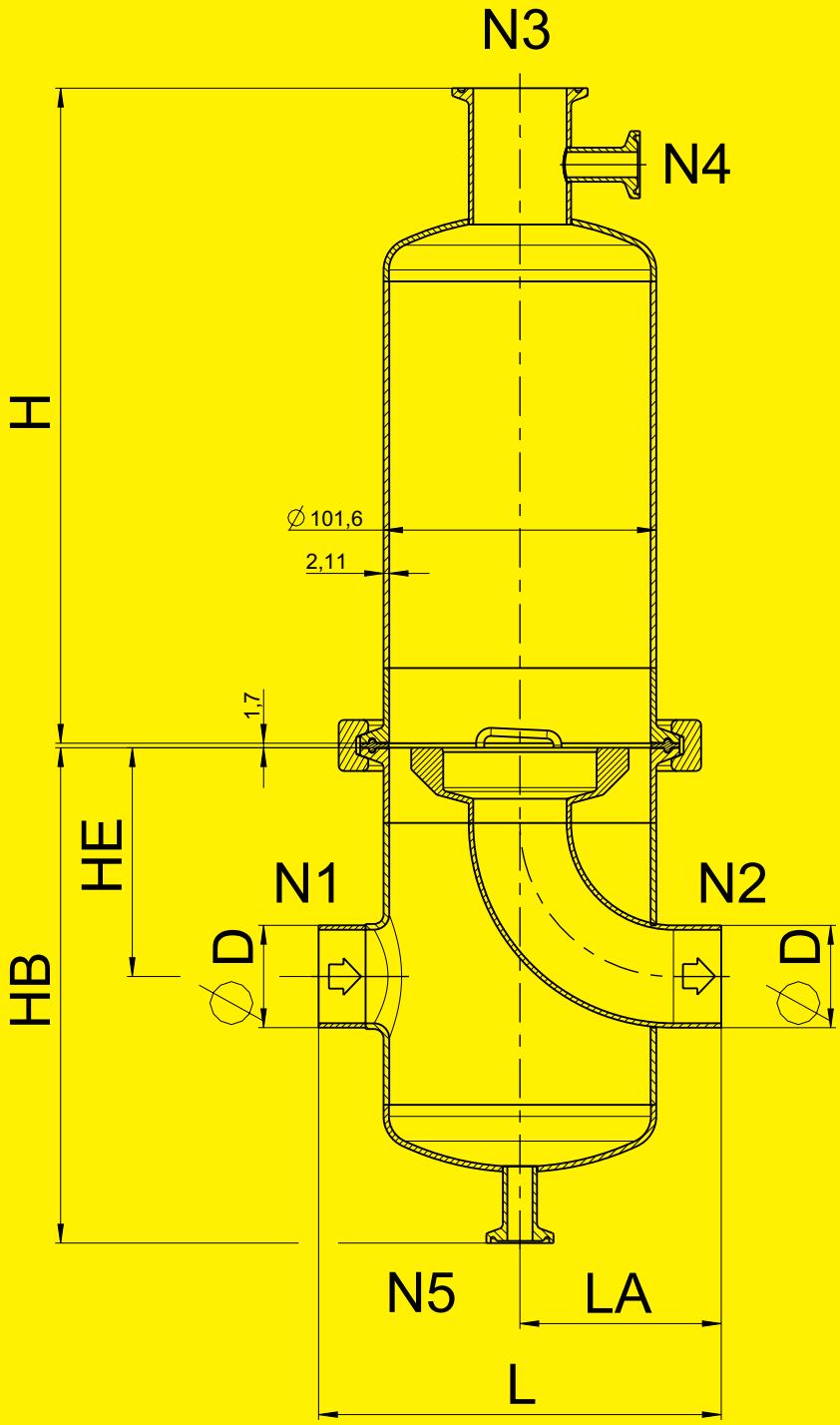
Content of the “Z” Premium Documentation Package
- Manual – english | german incl. multilingual CD
- Drawing
- Certificate incl. declaration of conformity for the manufacture and pressure testing of pressure equipment according to the pressure equipment directive 2014|68|EU
- Inspection report for pressure equipment
- Certificate of conformity for gaskets
- Measuring records of roughness and delta-ferrite
- Welding records
- Weld seam plan
- Measuring records of wall thickness
- Quality control plan
- Confirmation of pickling after the welding process
- Confirmation of electro polishing and passivation
- Certificate of marking control and traceability
- Material certificates
- Standard operating procedure “Pressure test“
- Standard operating procedure „Pickling“
- Standard operating procedure „Electro polishing“
- Standard operating procedure „Ultrasonic cleaning“
- Standard operating procedure „Measuring of surface roughness“
- Standard operating procedure „Testing method of delta-ferrite content“

Housing Overview

	Housing type	Pipe size	Inlet | Outlet	Height	Product code	Order code
	Gas 1-25	ISO – 33.7 × 2	Weld ends	5″	DG1-0-LEZ-I-S	8PJ28073300763LZ
	Gas 1-25	ISO – 33.7 × 2	Weld ends	10″	DG1-1-LEZ-I-S	8PJ28073310763LZ
	Gas 1-25	ISO – 33.7 × 2	Weld ends	20″	DG1-2-LEZ-I-S	8PJ28073320763LZ
	Gas 1-25	ISO – 33.7 × 2	Weld ends	30″	DG1-3-LEZ-I-S	8PJ28073330763LZ
	Gas 1-25	DIN – 29 × 1.5	Weld ends	5″	DG1-0-LEZ-D-S	8PJ28073300765LZ
	Gas 1-25	DIN – 29 × 1.5	Weld ends	10″	DG1-1-LEZ-D-S	8PJ28073310765LZ
	Gas 1-25	DIN – 29 × 1.5	Weld ends	20″	DG1-2-LEZ-D-S	8PJ28073320765LZ
	Gas 1-25	DIN – 29 × 1.5	Weld ends	30″	DG1-3-LEZ-D-S	8PJ28073330765LZ
	Gas 1-25	OD – 38.1 × 1.65	Weld ends	5″	DG1-0-LEZ-O-S	8PJ28073300762LZ
	Gas 1-25	OD – 38.1 × 1.65	Weld ends	10″	DG1-1-LEZ-O-S	8PJ28073310762LZ
	Gas 1-25	OD – 38.1 × 1.65	Weld ends	20″	DG1-2-LEZ-O-S	8PJ28073320762LZ
	Gas 1-25	OD – 38.1 × 1.65	Weld ends	30″	DG1-3-LEZ-O-S	8PJ28073330762LZ
	Gas 1-25	ISO – 33.7 × 2	TC 50.5	5″	DG1-0-LEZ-I-T	8PJ28073300764LZ
	Gas 1-25	ISO – 33.7 × 2	TC 50.5	10″	DG1-1-LEZ-I-T	8PJ28073310764LZ
	Gas 1-25	ISO – 33.7 × 2	TC 50.5	20″	DG1-2-LEZ-I-T	8PJ28073320764LZ
	Gas 1-25	ISO – 33.7 × 2	TC 50.5	30″	DG1-3-LEZ-I-T	8PJ28073330764LZ
	Gas 1-25	DIN – 29 × 1.5	TC 50.5	5″	DG1-0-LEZ-D-T	8PJ28073300766LZ
	Gas 1-25	DIN – 29 × 1.5	TC 50.5	10″	DG1-1-LEZ-D-T	8PJ28073310766LZ
	Gas 1-25	DIN – 29 × 1.5	TC 50.5	20″	DG1-2-LEZ-D-T	8PJ28073320766LZ
	Gas 1-25	DIN – 29 × 1.5	TC 50.5	30″	DG1-3-LEZ-D-T	8PJ28073330766LZ
	Gas 1-25	OD – 38.1 × 1.65	TC 50.5	5″	DG1-0-LEZ-O-T	8PJ28073300761LZ
	Gas 1-25	OD – 38.1 × 1.65	TC 50.5	10″	DG1-1-LEZ-O-T	8PJ28073310761LZ
	Gas 1-25	OD – 38.1 × 1.65	TC 50.5	20″	DG1-2-LEZ-O-T	8PJ28073320761LZ
	Gas 1-25	OD – 38.1 × 1.65	TC 50.5	30″	DG1-3-LEZ-O-T	8PJ28073330761LZ

	Housing type	Pipe size	Inlet | Outlet	Height	Product code	Order code
	Liquid 1-25	ISO - 33.7 × 2	Weld ends	5″	FG1-0-LEZ-I-S	8PJ28073300770LZ
	Liquid 1-25	ISO - 33.7 × 2	Weld ends	10″	FG1-1-LEZ-I-S	8PJ28073310770LZ
	Liquid 1-25	ISO - 33.7 × 2	Weld ends	20″	FG1-2-LEZ-I-S	8PJ28073320770LZ
	Liquid 1-25	ISO - 33.7 × 2	Weld ends	30″	FG1-3-LEZ-I-S	8PJ28073330770LZ
	Liquid 1-25	DIN – 29 × 1.5	Weld ends	5″	FG1-0-LEZ-D-S	8PJ28073300768LZ
	Liquid 1-25	DIN – 29 × 1.5	Weld ends	10″	FG1-1-LEZ-D-S	8PJ28073310768LZ
	Liquid 1-25	DIN – 29 × 1.5	Weld ends	20″	FG1-2-LEZ-D-S	8PJ28073320768LZ
	Liquid 1-25	DIN – 29 × 1.5	Weld ends	30″	FG1-3-LEZ-D-S	8PJ28073330768LZ
	Liquid 1-25	OD – 25.4 × 1.65	Weld ends	5″	FG1-0-LEZ-O-S	8PJ28073300772LZ
	Liquid 1-25	OD – 25.4 × 1.65	Weld ends	10″	FG1-1-LEZ-O-S	8PJ28073310772LZ
	Liquid 1-25	OD – 25.4 × 1.65	Weld ends	20″	FG1-2-LEZ-O-S	8PJ28073320772LZ
	Liquid 1-25	OD – 25.4 × 1.65	Weld ends	30″	FG1-3-LEZ-O-S	8PJ28073330772LZ
	Liquid 1-25	ISO – 33.7 × 2	TC 50.5	5″	FG1-0-LEZ-I-T	8PJ28073300769LZ
	Liquid 1-25	ISO – 33.7 × 2	TC 50.5	10″	FG1-1-LEZ-I-T	8PJ28073310769LZ
	Liquid 1-25	ISO – 33.7 × 2	TC 50.5	20″	FG1-2-LEZ-I-T	8PJ28073320769LZ
	Liquid 1-25	ISO – 33.7 × 2	TC 50.5	30″	FG1-3-LEZ-I-T	8PJ28073330769LZ
	Liquid 1-25	DIN – 29 × 1.5	TC 50.5	5″	FG1-0-LEZ-D-T	8PJ28073300767LZ
	Liquid 1-25	DIN – 29 × 1.5	TC 50.5	10″	FG1-1-LEZ-D-T	8PJ28073310767LZ
	Liquid 1-25	DIN – 29 × 1.5	TC 50.5	20″	FG1-2-LEZ-D-T	8PJ28073320767LZ
	Liquid 1-25	DIN – 29 × 1.5	TC 50.5	30″	FG1-3-LEZ-D-T	8PJ28073330767LZ
	Liquid 1-25	OD – 25.4 × 1.65	TC 50.5	5″	FG1-0-LEZ-O-T	8PJ28073300771LZ
	Liquid 1-25	OD – 25.4 × 1.65	TC 50.5	10″	FG1-1-LEZ-O-T	8PJ28073310771LZ
	Liquid 1-25	OD – 25.4 × 1.65	TC 50.5	20″	FG1-2-LEZ-O-T	8PJ28073320771LZ
	Liquid 1-25	OD – 25.4 × 1.65	TC 50.5	30″	FG1-3-LEZ-O-T	8PJ28073330771LZ

Gas Housing
1-round Adapter 25 (Code 7)



Nozzle description	
N3	TC sacc. to DIN 32676 – 1½" – 38.1 mm × 1.65 mm – TC 50.5 mm
N4	TC acc. to DIN 32676 – ½ " – 12.7 mm × 1.65 mm – TC 25 mm
N5	TC acc. to DIN 32676 – ½ " – 12.7 mm × 1.65 mm – TC 25 mm

Configuration of product code

DG1	-	X	-	L	E	Z	-	X	-	X

	Height
0	5"
1	10"
2	20"
3	30"

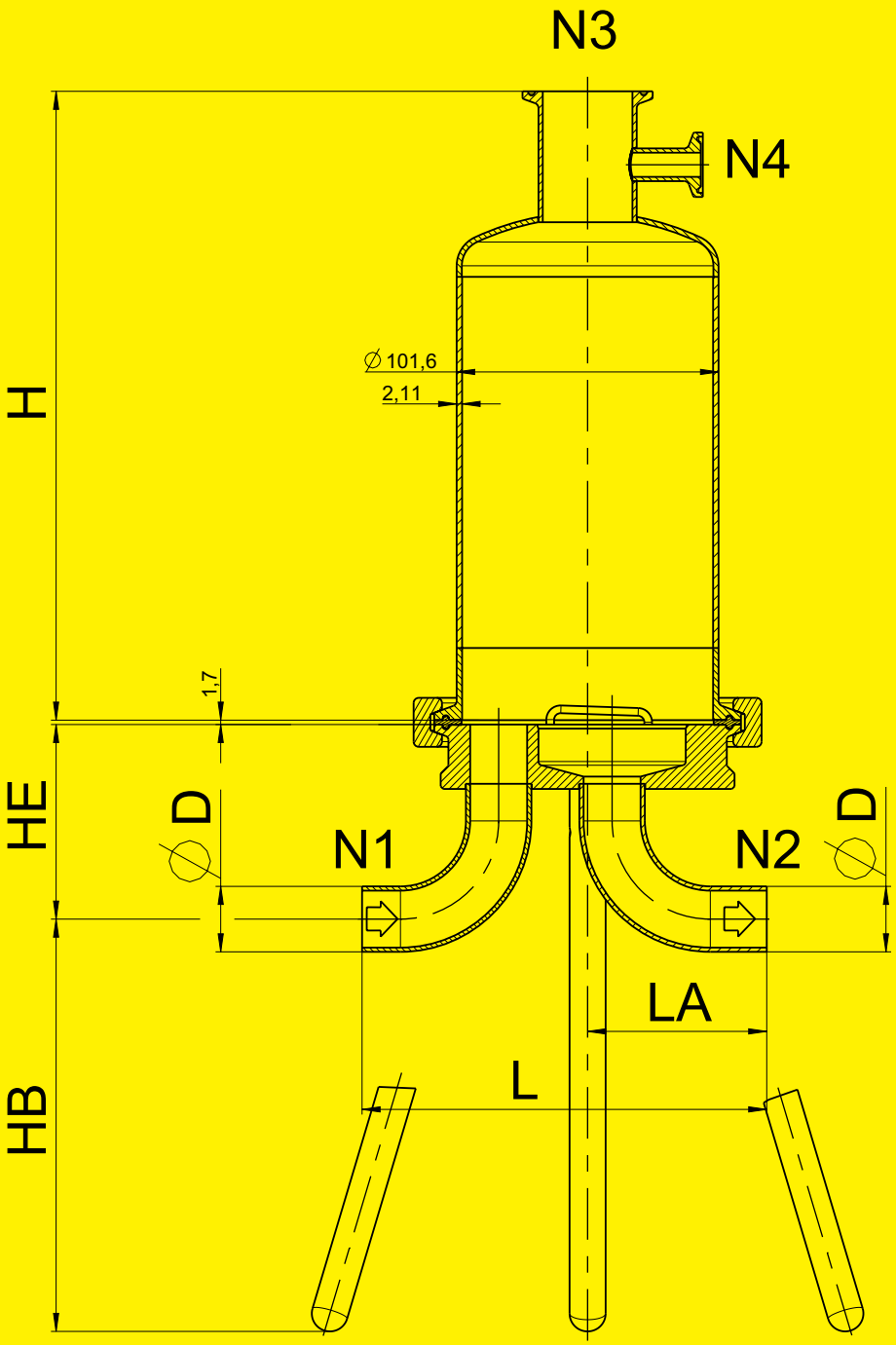
	Pipe size D
D	DIN – 29 mm × 1.5 mm
I	ISO – 33.7 mm × 2 mm
O	OD – 38.1 mm × 1.65 mm

	Connection N1 | N2
S	Orbital welding end
T	TC acc. to DIN 32676

Pipe size	Information to „L"	L +1 | -2	LA	HE +1 | -2	HB +1 | -2
DIN 29 mm × 1.5 mm	Orbital welding end	150 mm	75 mm	80.5 mm	184.5mm
	TC DIN 32676	222 mm	111 mm		
ISO 33.7 mm × 2 mm	Orbital welding end	152 mm	76 mm		
	TC DIN 32676	224 mm	112 mm		
OD 38.1 mm × 1.65 mm	Orbital welding end	150 mm	75 mm	85.2 mm	
	TC DIN 32676	222 mm	111 mm		

„H"	+2 | -5
5"	244 mm
10"	384 mm
20"	634 mm
30"	884 mm

Liquid Housings
1-round Adapter 25 (Code 7)



Nozzle description	
N3	TC acc. to DIN 32676 – 1 ½" – 38.1 mm × 1.65 mm – TC 50.5 mm
N4	TC acc. to DIN 32676 – ½" – 12.7 mm × 1.65 mm – TC 25 mm

Configuration of product code

FG-1	-	X	-	L	E	Z	-	X	-	X

	Height
0	5"
1	10"
2	20"
3	30"

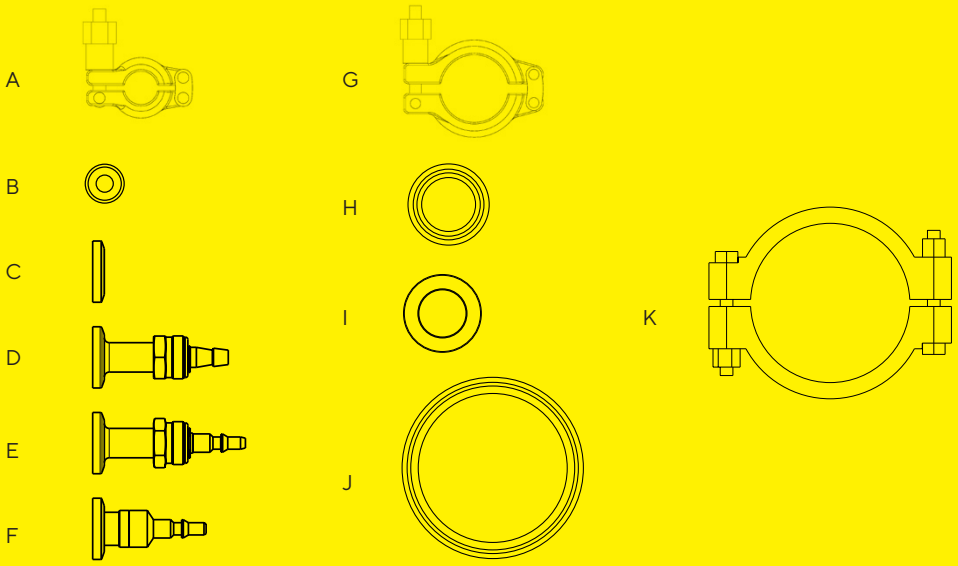
	Pipe size D
D	DIN – 29 mm × 1.5 mm
I	ISO – 33.7 mm × 2 mm
O	OD – 25.4 mm × 1.65 mm

	Connection N1 | N2
S	Orbital welding end
T	TC acc. to DIN 32676

Pipe size	Information to „L"	L +1 | -2	LA	HE +1 | -2	HB + | -5	DF + | -10
DIN 29 mm × 1.5 mm	Orbital welding end	174 mm	74.5 mm	75.5 mm	160 mm	258 mm
	TC DIN 32676	246 mm	110.5 mm			
ISO 33.7 mm × 2 mm	Orbital welding end	164 mm	69.5 mm			
	TC DIN 32676	236 mm	105.5 mm			
OD 25.4 mm × 1.65 mm	Orbital welding end	157 mm	69.5 mm			
	TC DIN 32676	229 mm	105.5 mm			

„H"	+2 | -5
5"	244 mm
10"	384 mm
20"	634 mm
30"	884 mm

Spare-Parts



For	Optional spare parts		Order code
N4	A	Clamp for TC 25	7ZSB--0051
	B	Gasket ½"	
		EPDM (2 pieces)	7EDECV0001
		Silicone (2 pieces)	7EDSCV0001
		Fluoroelastomer (2 pieces)	7EDVCV0001
		PTFE with Fluoroelastomer core (2 pieces)	7EDWCV0001
	C	Blind TC for TC 25 (2 pieces)	7ZAL-V0005
	D	Pharma valve with TC 25	7ZMLN-0048
	E	Pharma valve with RBE03 and TC 25	7ZVLN-0121
	F	Automatic male plug closure RBE03 and TC 25	7ZMLN-0015
N3	G	Clamp for TC 50.5	7ZSB--0052
	H	Gasket 1 ½"	
		EPDM (2 pieces)	7EDECV0003
		Silicone (2 pieces)	7EDSCV0003
		Fluoroelastomer (2 pieces)	7EDVCV0003
		PTFE with Fluoroelastomer core (2 pieces)	7EDWCV0005
	I	Blind TC for TC 50.5 (2 pieces)	7ZAL-V0006
Housing closure	J	Housing gasket 4"	
		EPDM (2 pieces)	7EDECV0007
		Silicone (2 pieces)	7EDSCV0007
		Fluoroelastomer (2 pieces)	7EDVCV0007
		PTFE with EPDM core (2 pieces)	7EDXCV0001
	K	2-piece Clamp for TC 4" – with screws, washers	7ZSB--0030

Removable Heater (Optional Spare Part)

The housing heaters offer tight temperature control and advanced functionality, while complying with strict safety regulations.

The ELTC-14 control unit is a stand alone solution, which features a user friendly digital display and a high | low temperature alarm relay. It is CE tested and marked for both electrical and thermal safety.

Order information

Order code	Height | electrical power
7ZE---0030	5", Height 155 mm, 50 W max.
7ZE---0031	10", Height 270 mm, 100 W max.
7ZE---0032	20", Height 540 mm, 200 W max.
7ZE---0033	30", Height 810 mm, 300 W max.

Operation data	
Supply Voltage	230 Volt + | -10%, 50 Hz
Switching Capacity	16 Ampere | 230 Volt
Measuring Input	PT 100 DIN 2-Wire
Adjustment Range	0 ... +100°C
Ambient Range	-30 ... +60°C
Protection Type Controller	IP65 Protection Class I
Protection Type heating jacket	IP54 Protection Class II
Outside material	Glass fabric (PTFE coated)
CE Conformity	2004|108|EC
	2006|95|EC
	2011|65|EC

Lengths of Cables	
Power supply cable (black)	3.0 m
Data cable (red)	2.0 m

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

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For further contacts, visit
www.sartorius.com

Status: 07 | 2020

SARTORIUS

Product Datasheet

Sartocheck® 5 Plus Filter Tester

Keeps Your Risk Factors Under Complete Control

New Software Release
Q1 2023 - Version 2.2.1

Product Information

The Sartocheck® 5 Plus represents the ideal intersection point of today's most relevant industry requirements for filter integrity testing within demanding GMP environments. A combination of a unique approach to Quality Risk Management (QRM) as well as optimal data integrity, intuitive usability, and minimized risk factors for Health, Safety, and Environment (HSE) set a new standard for filter integrity test devices.

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Surpass the Requirements of QRM
The regulatory focus on QRM (cf. ICHQ9 and the new Annex 1 written by EMA in cooperation with the US-FDA, WHO, and PICs) also applies to filter integrity testing, as a fundamental element of sterility assurance.

The Sartocheck® 5 Plus Filter Tester uses program-specific parameters allowing the automatic identification of testing anomalies before or during the test. This prevents time-consuming, costly variations, potential drug recalls, and 483 warning letters.

Experience the Comfort of Intuitive Usability
An optimal user experience speeds up process workflows due to intuitive guidance and ease of use. The high-quality touchscreen of the Sartocheck® 5 Plus Filter Tester provides a unique viewing angle, an intuitive user interface, a logical menu structure, and simple data entry options. This allows straightforward programming of tests and QRM enhancement features, as well as error-free operation in GMP production environments.

Reach the Ultimate Level of Data Integrity
Filter integrity test values are part of the batch protocol and are used to justify the drug release. Long-term reliable data is crucial to avoid quality deviations and potential 483 warning letters.

The integrity and security of filter integrity test data must not be seen only as an IT problem, but also as a potential global business risk. Low standards of data integrity and security may not only jeopardize the activities of the drug manufacturing company, but more critically, endanger the health of patients.

Discover the Simplicity of HSE
Integrity testing often involves the use of chemicals and hazardous materials, e.g., alcohol. The Sartocheck® 5 Plus is certified for use in explosion-hazardous areas (ATEX) and is compatible with all current cleaning agents and VHP. This ensures maximum safety for operators and manufacturing facilities.

Quality Risk Management
- Automatic detection of incorrect test setups
  - Program-specific min. and max. values for volume determination
  - Program-specific min. diffusion | intrusion values
  - Program-specific min. flow at pressure end during a bubble point test
- Automatic detection of abnormal test conditions
  - Detection of abnormal pressure increase
  - Detection of environmental temperature outside prerequisite conditions and temperature changes (roadmap – requires sensor)
  - Detection of unstable test values (roadmap – pat. pending)
- Self-test at booting and before each test
- Comprehensive Failure Mode Effects Analysis (FMEA), including instructions for setting program-specific QRM values to avoid false passed and false failed test results
- Calculation tool for the impact of unlikely calibration offsets

Usability
- Intuitive iF-design-rewarded Human Machine Interface (HMI)
- 12.1" bright touchscreen with a ± 88° viewing angle
- Large digital keypad - no need for a pen – compatible with glove use
- 10 system languages
- LDAP: log on with network user credentials
- Automatic test time for faster testing
- Data transfer
- Automation by OPC UA or Modbus TCP
- Additional keyboards (Korean and Cyrillic)
- LDAP group-based role management
- Filtering of displayed audit trail events
- Audit trail export in a digitally signed write-protected PDF
- Remote administration via OPC UA
- Memory management (21CFR Part 11)
- Printing via printer server
- DNS name support
- Scheduled export of the audit trail in PDF format
- Improved program parameters for large crossflow system (TFF) systems

Data Integrity
- Custom Linux-based OS with SSB custom architecture
- Audit trail with time zone-synchronized (NTP) events
- Write-protected and constantly monitored root file system
- Encrypted double data backup | redundant data storage
- 4 eyes principle | electronic signatures
- Comprehensive and flexible role management
- Locking out user after X number of unsuccessful login attempts
- Serial number of the device in every audit trail entry
- Easy to read audit trail on the screen
- Harmonized time representations
- A major update of the root file system of the SC5 in the Q2 2022 release will further strengthen the data security aspects of the software
- Mandatory "Why" comment when modifying program parameters (Q2 2022)
- Blocking of abusive test attempts (Q2 2022)

Request the Data Integrity statement for more details.

CCS, HSE | OSH
- Splash-proof (IP64)
- Ex-proof (ATEX IECEx & FM certified)
- Safe testing and re-testing of alcohol-wetted filters
- Continuous and clear visualization of pressure status
- Resistant to all current cleaning agents
- H_2O_2-vapor-resistant (VHP)
- PFA tubings (FDA 21 CFR 177 and USP Class VI compliant)
- Optional kit for automated cleaning of the pneumatics with up to 0.5 M NaOH at 50 °C, available in Q3 2022 (requires at least software version 2.0.0). See the Contamination Control Strategy documentation for additional information
- Optional accessory kit for backflow protection (26787---AK---EV)

Technical Data

Test Methods
Diffusion
Bubble point (detection by over proportionality)
Combined diffusion and bubble point
Water intrusion test
Pressure drop | leak test

Measuring Ranges	
Diffusion and intrusion test pressure	50.0 – 6,600.0 mbar | 0.725 – 95.725 psi
Programmable max. diffusion flow	0.011 – 4,800.000 mL/min.
Programmable max. intrusion water flow	0.006 mL/min. – 60.000 mL/min.
Max measurable | displayable diffusion flow	24,000.00 mL/min. (5 times the max. programmable value)
Max. measurable | displayable intrusion water flow	300.00 mL/min. (5 times the max. programmable value)
Programmable min. bubble point	250.0 – 6,550.0 mbar | 3.626 – 95.000 psi
Programmable pressure drop (not higher than the test pressure)	0.5 – 6,600.0 mbar | 0.007 – 95.725psi
Sample net volume with volume measurement	
▪ with int. reference vessel	14 L
▪ with ext. reference vessel	150 L
Max. sample net volume for pressure drop test	1,000 L

Power Supply	
Power requirements	100 – 240 V AC at 50 | 60 Hz
Max. power input	74 W
Average power usage	66 W
Power consumption in standby mode	14.8 W

A country-specific cable is delivered with each device.

Internal battery

The Sartocheck® 5 is equipped with an internal battery. This battery (CR2032) contains less than 0.3 g lithium.

Pneumatics	
Max. inlet pressure	8,000 mbar | 116 psi
Overpressure protection	Max. inlet pressure + 4,000 mbar
Min. inlet pressure	4,000 mbar | 58 psi
Internal reference volume	1,023 mL conforming to Pressure Equipment Directive 2014/68/EU max. Pressure = 12 bar pressure certificate

Measuring Accuracies	
Measured pressure	± 0.1% full scale (± 7.2 mbar | ± 0.104 psi)
Measured pressure drop	0.2% of the measured value before rounding
Volume determination	± 4%
Diffusion	± 5% or 0.05 mL/min, whichever is higher
Intrusion	± 5% or 0.05 mL/min, whichever is higher
Bubble point	± 50 mbar | 0.73 psi, can be improved to ± 25 mbar | 0.36 psi (configurable pressure steps)
Accelerated bubble point	± 50 mbar | ± 0.73 psi from the starting pressure to one pressure step above the min. bubble point

Dimensions, Weight, and Noise	
Dimensions (W × D × H)	348 × 379 × 286 mm
Weight	16.8 kg
Weight of the packaging	2.2 kg
Cargo | gross weight	20.6 kg
Cargo volume	95,304 cm^3
Cargo dimensions	570 × 440 × 380 mm
Max. noise at 1 m during depressurization with venting tubings	68 dB(A) at 6,600 mbar (95.7 psi) 51 dB(A) at 3,000 mbar (47.9 psi)

Manufacturing Site

Designed, developed, and manufactured in Germany
Otto-Brenner Strasse 20
Goettingen, Germany

End-user Training

The Sartocheck® comes with end-user training.

Materials of Construction and Roughness
All materials used for the external surfaces and the fluid paths are animal free.

External Surfaces
▪ Ra 1.6 µm or better
▪ Stainless steel 304L
▪ Heat strengthened glass (see “Screen and Protective Glass”)
▪ Plastic polymer (Edistir® polystyrene PBBE free) painted with chemical resistant Alexit finishing coat B412
▪ Aluminum painted with chemical resistant Alexit finishing coat B412
▪ Rubber feet: Taber H-18 abrasion resistant (ASTM-501C)

Pneumatic Fluid Path of the Sartocheck® 5 Plus
▪ Ra 1.6 µm or better
▪ Aluminum (inlet valve block, no potential product contact)
▪ Stainless steel 304L (process valve block)
▪ Stainless steel 316L (connectors)
▪ EPDM (connector gaskets), FDA 21 CFR 177 and USP Class VI (A)
▪ PFA tubings, FDA 21 CFR 177 and USP Class VI (A)
▪ PTFE (valve block membrane FDA 21 CFR 177 and USP Class VI (A)

Pneumatic Fluid Path of the Accessory Kit for External Venting
▪ Ra 1.6 µm or better
▪ Stainless steel 304L (valves)
▪ Stainless steel 316L (connectors)
▪ EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)

External Tubings (Inlet and Test Tubing)
▪ PFA tubings, FDA 21 CFR 177 and USP Class VI (A)
▪ Stainless steel 316L (connectors)
▪ EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)
▪ Sintered Polyethylene (inlet filter)
▪ Polypropylene (inlet filter housing)
▪ Stainless steel 316L Parker nipple

Screen and Protective Glass	
Size	12.1" (Format 16:10; 262.6 × 164.7 mm | 10.34 × 6.48 inch)
Type	TFT LED-Backlit color
Resolution	1,280 × 800 pixels
Luminosity	400 CD/m^2
Viewing angle vertical and horizontal	± 88° (total 176°)
Shock resistance	Thermally toughened glass DIN EN 12150-1; IEC 60068-2-75
Antiglare	LS Touch Gloss 85 ± 10 | 60° on front side

Connectors and Ports
All connectors on the device are specifically defined in order to avoid mix up between different connections. E.g., the test tubing can only be connected to the outlet of the device.

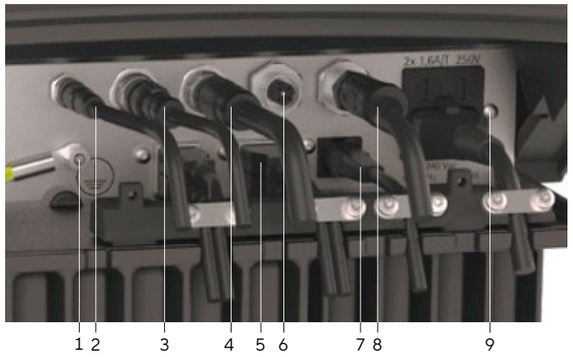
Pneumatic Connectors	
Inlet tubing towards pressurized line	Parker nipple (Parker reference 26SFAW13MXN)
Inlet tubing towards device	Staubli RBE03 female
Test tubing towards sample to be tested	Staubli RBE03 female

Pneumatic Tubings
All pneumatic tubings have been leak-tested at the end of manufacturing. Use only original test tubings of original length with original connectors to avoid any mix-up.

Communication Ports
▪ Industrial automation for OPC UA and Modbus TCP
▪ Ethernet RJ45 for networking and data transfer
▪ USB (4 ports) for software upgrades, barcode reader, and USB printer

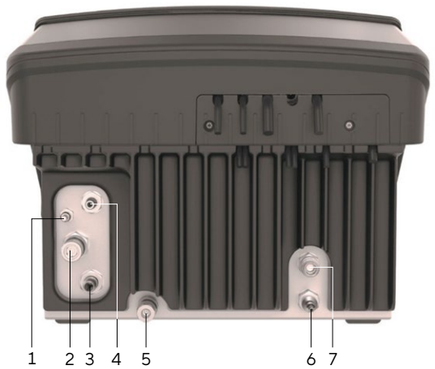
Operating Conditions	
Environmental temperature and humidity according to IEC 61010-1	0 °C to 40 °C (32 – 104 °F) From 0 °C to 31 °C 80% RH From 31 °C to 40 °C linearly decreasing to 50% RH
Altitude	100 m below sea level to 3000 m above sea level
Ingress protection rating of the device as per EN 60529 | IEC 60529	IP64 under normal conditions IP4X for use in potentially explosive atmospheres
Ingress protection of the Accessory Kit for External Venting as per EN 60529 | IEC 60529	IP65
Explosion-prone areas (device only)	Zone 2, Groupe II-B (IECEx, ATEX) | Class 1 Zone 2 Group II-B (USA)
Explosion-prone areas (Accessory Kit for Venting)	Zone 1 Group II-B (IECEx, ATEX) | Class 1, Div. 1, Zone 1 Group II-B (USA)

Connectors on the backside



1 Earth
2 Future environmental, temperature sensor
3 External pressure sensor
4 External valves
5 4 × USB (e.g. printer)
6 Future extender box
7 RJ45
8 Industrial automation
9 Power

Back cover closed



1 Device cleaning
2 Outlet | test tubing
3 Sample vent
4 Device vent
5 Ext. reference tank
6 Inlet pressure, max. 8 barg,
7 External valves pressure supply

Fixation of cables

Operating System and Memory

- Custom Linux Distribution made by Sartorius
- Flash memory 4 GB
- RAM 2 GB
- Internal inaccessible SD card 8 GB
- CPU MSC NanoRISC i.MX6 D 800 MHz

Memory Capacity

The memory can hold approximately 21,900 test results.
At a rate of 10 tests per day, 365 days per year, the memory will be full after approximately 6 years.

Test Result Calculation, Evaluation, and Rounding

The test evaluation is done before the rounding, meaning that, e.g., a measured diffusion value with 16 decimals of 4.4000000000000001 mL/min. will give a failed test if the max. diffusion value is set to 4.400 mL/min. The test result rounding is done according to the tie-breaking rule called “round half to even”. This is the default rounding mode used in IEEE 754 computing functions and operators.

Storage and Transportation Conditions

From -10 °C to +60 °C (14 – 140 °F) at 90% RH noncondensing humidity.
The original cardboard box is single-use shipping only.
For subsequent shipping, please use the solid transportation box 26787---ST (see accessories).

Language Options

- English
- German
- French
- Spanish
- Italian
- Mandarin (simplified)
- Portuguese (Brazilian)
- Japanese
- Korean
- Russian

Cleaning and Chemical Compatibility of External Surfaces (Based on Alexit Lacquer Compatibility)

Do not use any abrasive cloth.
Only smooth cloths or towels are allowed.

- Spor-Klenz® Ready-To-Use Cold Sterilant
- 3% Hydrogen Peroxide WFI Sterile Solution
- Septihol® Sterile Alcohol Solution 70% IPA
- Water for injection
- Sodium hydroxide (NaOH) 10%
- Hydrochloric acid (HCL) 20%
- Sulfuric acid (H2SO4) 20%
- Acetic acid 10%
- Ammoniac 10%
- Quaternary ammonium compounds 0.2%
- Cleansinald (Quaternary ammoniums blended with alkyl amines)
- Bacterianos (Glutaraldehyde 0.5 mg/g and didecyldimethyl-ammonium chloride 1.2 mg/g; pH 3 – 5, contact time > 15 min.)
- Aniospray (Ethanol 226 mg/g, Chlorure de didécyldiméthyl-ammonium 0.53 mg/g, chlorhydrate de polyhexaméthylène biguanide 0.64 mg/g contact time > 15 min.)
- Amphospray (Ethanol 327.4 mg/g, N-(3-aminopropyl)-Ndodé-cylpropane- 1,3-diamine 0.33 mg/g), chlorure de didécyldiméthylammonium 1.09 mg/g), chlorhydrate de polyhexaméthylène biguanide 0.96 mg/g)
- Formaldehyde 37%
- Sodium hypochlorite 6%
- Ethanol (60%, 70%, and pure)
- Acetone (pure)
- Ethyl acetate (pure)
- Minncare Cold Sterilant
- Vaporized Hydrogen Peroxide (VHP) at 1400 ppm

Cleaning of Internal Pneumatics

Use only the original Accessory Kit for Cleaning (available Q3 2022)

Warning!
Inflammable or explosion-prone liquids must not be used for internal cleaning because the Accessory Kit for Cleaning is not compliant to hazardous areas or liquids.

Use the following cleaning agents:
- Sodium hydroxide up to 0.5 M at 25 °C (77 °F)
- Citric acid 10% at 25 °C (77°F)
- Sodium hypochlorite 10% at 25 °C (77 °F)
- 3% Hydrogen Peroxide at 25 °C (77 °F)

Sartocheck® 5 and 5 Plus Filter Tester Comparison

Feature	Sartocheck® 5	Sartocheck® 5 Plus
QRM-related program parameters	No	Yes
Automation (OPC UA and Modbus TCP)	No	Yes
Data integrity	Identical	Identical
HSE – ATEX | IECEx | FM	Identical	Identical
Usability	Identical	Identical
Accuracy	Identical	Identical
Cleanability	Identical	Identical
Accessory kits (External Venting Kit and Cleaning Kit)	Compatible (cleaning kit available in Q3 2022)	Compatible (cleaning kit available in Q3 2022)
Included software upgrades	Selected upgrades are included until the software release mid of 2024	Yes – All upgrades until the software release mid of 2024

Ordering Information

Sartocheck® Filter Tester

Description	Article No.
Sartocheck® 5 Filter Tester	26787---FT

Equipment included in 26787---FT
Sartocheck® 5 Filter Tester
Inlet tubing for compressed gas 2m (26787---IT)
Test tubing 2 m (26787---TT---02)
Test certificate
Calibration certificate
Installation and operating instructions
Power cord (region-specific)
Screw driver (T20 × 100) for fixation of cables
Networking cable (RJ45)
Printer cable (USB)

Sartocheck® Plus Filter Tester

Description	Article No.
Sartocheck® 5 Plus Filter Tester	26787---FT---P

Equipment included in 26787---FT---P
Sartocheck® 5 Plus Filter Tester
Inlet tubing for compressed gas 2 m (26787---IT)
Test tubing 2 m (26787---TT---02)
Test certificate
Calibration certificate
Installation and operating instructions
Risk assessment for integrity testing | FMEA (PDF)
Power cord (region-specific)
Screw driver (T20 × 100) for fixation of cables
Networking cable (RJ45)
Printer cable (USB)

Accessories and Spare Parts

Description	Article No.
USB printer (without paper)	YDP30
Archivable paper 90 m and ink ribbon	69Y03285
Archivable self-adhesive paper 90 m and ink ribbon	69Y03286
Thermal paper 5 rolls of 24 m	69Y03287
Self-adhesive thermal paper 5 rolls of 13 m	69Y03288
Inlet tubing for compressed gas 2 m	26787---IT
Test tubing 2 m	26787---TT---02
Test tubing 5 m	26787---TT---05
Test tubing 15 m	26787---TT---15
Test tubing for external venting	26787---TT-AKEV
Complete tubing-cable wrap for AKEV 2 m	26787---02-AKEV
Complete tubing-cable wrap for AKEV 5 m	26787---05-AKEV
Accessory Kit for External Venting	26787---AK---EV (max. 10 accessory kits per device due to calibration data)
Tubing for “device vent”	26787---VT---DE
Tubing for “sample vent”	26787---VT---SA
Accessory kit for cleaning of the pneumatics*	
Germany (German manual)	26787---AKDE-CL
UK, India & US | Canada (English manual)	26787---AKEN-CL
France (French manual)	26787---AKFR-CL
Italy (Italian manual)	26787---AKIT-CL
Spain & Argentina (Spanish manual)	26787---AKES-CL
Portugal & Brazil (Portuguese manual)	26787---AKPT-CL
China (Chinese manual)	26787---AKCN-CL
Japan (Japanese manual)	26787---AKJP-CL
Korea (Korean manual)	26787---AKKR-CL
Russia (Russian manual)	26787---AKRU-CL
Switzerland, Belgium & Canada (English, German, French & Italian manuals)	26787---AKVA-CL
South Africa , Australia | New Zealand, Israel and Denmark (English manual)	26787---AKVB-CL

* For more details, please refer to the Contamination Control Strategy (CCS) datasheet.

Description	Article No.
10 L pressure vessel including safety valve and manometer, certified for EU	26787---AKPV-EU
Additional waste vessel for the accessory kit for cleaning	26787---AKWV-CL
Barcode Scanner (None ATEX)	26787---BS
External reference volume	26787---ER
Additional tubing for the external reference volume	26787---TE—RV
Solid transportation box for the Sartocheck® 5 | 5 Plus	26787---ST
Midisart® Test Manifold for parallel bubble point	1Z-LB-0002
Triclamp 25 mm – Staubli nipple RBE03 open	7ZML--0009
Triclamp 25 mm – Staubli nipple RBE03 closed	7ZML--0015
Triclamp 50.5mm - Staeubli-nipple (closed) RBE03.7 Alternative adapter with EPDM gasket	7ZML--0012 7ZML--0055
Triclamp 50.5 mm - Staeubli-coupling (closed) RBE03 Alternative adapter with EPDM gasket	7ZML--0019 7ZML--0056
Luer lock male – Staubli nipple RBE03 open	7ZV--0115

Services

Description	Article No.
Validation package for Sartocheck® 5 | 5 Plus	26787---V3---FT
Sartocheck® 5 | 5 Plus installation	S872QINST
Sartocheck® 5 | 5 Plus installation pack (incl. travel exp.)	S872QINSTP
Valve Kit installation	S873IINST
Valve Kit installation pack (incl. travel exp.)	S873IINSTP
Sartocheck® 5 | 5 Plus IQ | OQ	S872QIQOQ
Sartocheck® 5 | 5 Plus IQ | OQ service pack (incl. travel exp.)	S872QIQOQP
Valve Kit IQ | OQ	S873IIQOQ
Valve Kit IQ | OQ service pack (incl. travel exp.)	S873IIQOQP
Service level agreement Advanced	S872QSLAA
Service level agreement Comprehensive	S872QSLAC
Service level agreement Essential	S872QSLAE

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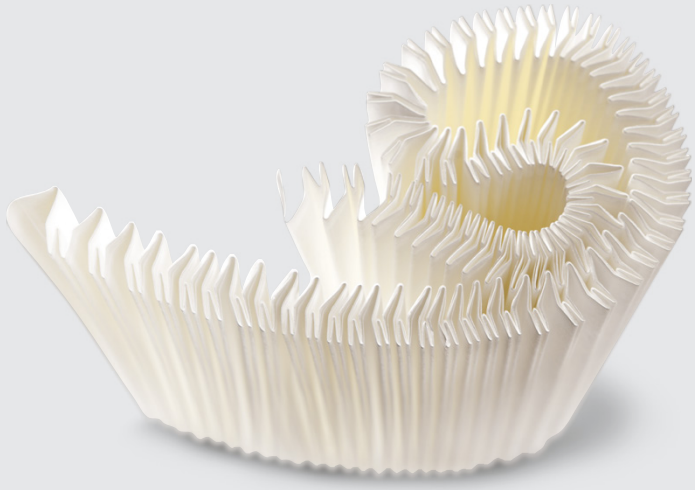
SARTORIUS

Product Datasheet

Sartopore® Platinum

Sterilizing-Grade Filter Elements



Product Information

- Highest product yield due to lowest adsorption
- Excellent wettability ensures to low flushing volumes and high reliability of integrity testing
- High filtration capacity enables use of less filter elements or smaller filter sizes
- Smaller dimensions of single-use assemblies necessary: smaller bags, less tubing

Unique Surface Modification

A patented membrane hydrophilization process is used to permanently modify the membrane surface.

This technology provides those membrane surface properties that are responsible for the outstanding wettability and low protein binding character of the Sartopore® Platinum membrane, even after extreme thermal and chemical stress, without affecting wettability and integrity testing.

Perfect Solution for Single-Use Processes

The perfect wettability of the PES membrane leads to drastic reduction of the required flushing volumes (up to 95% less water needed) which is highly beneficial especially for for single-use processes. Due to the low flushing volume the required waste bags can be significantly downsized by which costs are reduced and handling is optimized.

Maximum Yield for High-Value Products

Besides high filtration capacity the surface modification leads to lowest protein adsorption of any PES membrane in the market by which product yield can be maximized.

Reliable Integrity Testing

Imperfect wetting is the most frequent reason for failed integrity tests. Especially for single-use processes the re-wetting possibility is limited.

The extraordinary wetting behavior of Sartopore® Platinum thus helps to eliminate this important risk factor. Using Sartopore® Platinum leads to highly reliable integrity tests.

Applications

- Production of high-value biologicals like monoclonal antibodies
- Final conjugated bulk
- Point of fill filtration
- Especially beneficial for single-use filtration processes
- Blood and plasma processes
- Ophthalmics

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® Platinum filters.

Our services provide
- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements. Our local teams of validation experts support you with our tailored and consultative approach to determine the most cost-effective solution and give you the confidence you need to succeed.

Technical Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar | 36 psi [ml/min]	Min. Bubble Point [bar | psi]
Cartridges, T-Style Maxicaps®, Maxicaps®			
Size 1	1.0 m² | 10.8 ft²	25	3.5 | 51
Size 2	2.0 m² | 21.5 ft²	50	3.5 | 51
Size 3	3.0 m² | 32.3 ft²	75	3.5 | 51
Midicaps® | Gamma Midicaps®			
Size 7	0.065 m² | 0.7 ft²	4	3.5 | 51
Size 8	0.13 m² | 1.4 ft²	5	3.5 | 51
Size 9	0.26 m² | 2.8 ft²	7	3.5 | 51
Size 0	0.52 m² | 5.6 ft²	14	3.5 | 51
Capsules | Gamma Capsules			
Size 4	0.021 m² | 0.22 ft²	1.1	3.5 | 51

Max. Allowable Differential Pressure

Cartridges
5 bar | 72.5 psi at 20 °C
2 bar | 29 psi at 80 °C

T-Style Maxicaps®, Maxicaps®, Midicaps® | Gamma Midicaps®
5 bar | 72.5 psi at 20 °C
3 bar | 43.5 psi at 50 °C

Capsules | Gamma Capsules Size 4
4 bar | 58 psi at 20 °C
2 bar | 29 psi at 50 °C

Materials

Prefilter Membrane
Polyethersulfone, asymmetric

Endfilter Membrane
Polyethersulfone, asymmetric

Support Fleece
Polypropylene (In-line steam sterilizable and autoclavable)
Polyester (γ-irradiatable or γ-irradiatable | autoclavable)

Core
Polypropylene

End Caps
Polypropylene

Capsule Housing
Polypropylene

O-Ring
Silicone
(other materials on request)

Max. Allowable Back Pressure

2 bar | 29 psi at 20 °C
(for all elements)

Pore Size Combination

0.45 µm + 0.2 µm

Regulatory Compliance

- For release, each individual element is tested for integrity by bubble point and diffusion test
- Fully validated as sterilizing-grade filters according to ASTM current F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non pyrogenic according to USP Bacterial Endotoxins
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

Sterilization

Cartridges
In-Line Steam Sterilization (dry or wet steaming)
Max. 134 °C, 0.3 bar, 20 min
Min. 25 Sterilization Cycles

or

Autoclaving
Max. 134 °C, 2 bar, 30 min
Min. 25 Sterilization Cycles

Midicaps® and Capsules
Autoclaving
Max. 134 °C, 2 bar, 30 min
Min. 25 Sterilization Cycles (Midicaps®)
Min. 5 Sterilization Cycles (Capsules)

Gamma Midicaps® and Gamma Capsules
Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

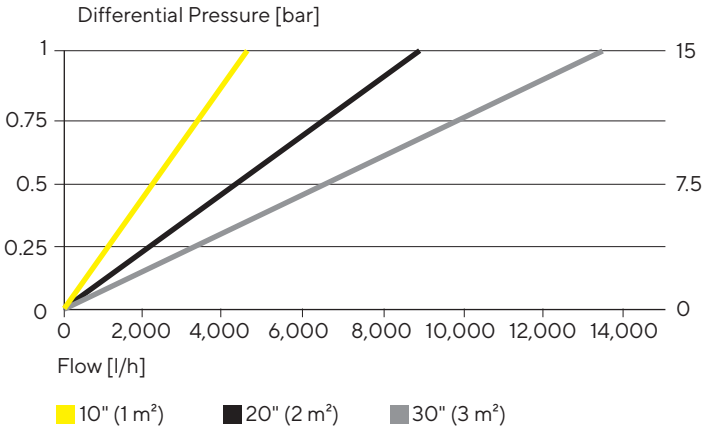
T-Style Maxicaps® and Maxicaps®
Autoclaving
Max. 134 °C, 2 bar, 30 min
Min. 5 Sterilization Cycles

or

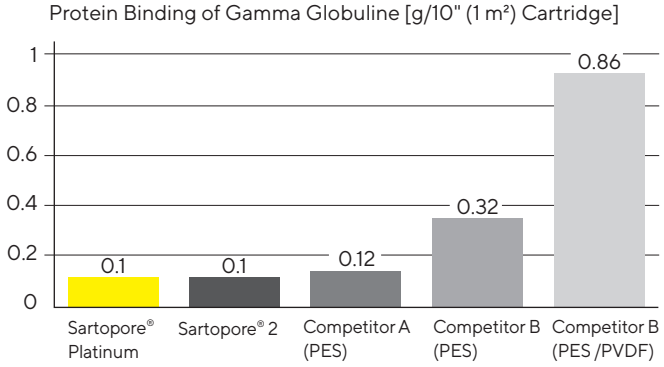
Gamma Irradiation
≤ 50 kGy
1 Sterilization Cycle

Performance

Water Flow Rates 10", 20", 30"



Unspecific Protein Binding



Technical References

Validation Guide	2665259
Extractables Guide	2650008

Ordering Information

Cartridge

549	25	07	H	■

Adapter
25: 2 flange bayonet adapter with 226 double o-ring

Filter Size
1: 1.0 m² | 10.8 ft² (10")
2: 2.0 m² | 21.5 ft² (20")
3: 3.0 m² | 32.3 ft² (30")

(Standard with silicone o-ring optional with EPDM or Fluoroelastomer o-ring).

T-Style Maxicaps®

549	83	07	H	■	G-	■	■

Filter Size
1: 1.0 m² | 10.8 ft² (10")
2: 2.0 m² | 21.5 ft² (20")
3: 3.0 m² | 32.3 ft² (30")

Sterilization
G-: γ-irradiatable and autoclavable

Connector Inlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
Y: 1"single stepped hose barb

Connector Outlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
Y: 1" single stepped hose barb

Maxicaps®

549	73	07	H	■	G-	■	■

Filter Size
1: 1.0 m² | 10.8 ft² (10")
2: 2.0 m² | 21.5 ft² (20")
3: 3.0 m² | 32.3 ft² (30")

Sterilization
G-: γ-irradiatable and autoclavable

Connector Inlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
F: ¾" tri-clamp 25 mm

Connector Outlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
F: ¾" tri-clamp 25 mm

(Optional with vent valve design for connection of integrity tester. Example: 5497307H1G-SOIT)

Midicaps® | Gamma Midicaps®

549	53	07	H	■	■	■	■	--	■

Filter Size
7: 0.065 m² | 0.7 ft²
8: 0.13 m² | 1.4 ft²
9: 0.26 m² | 2.8 ft²
0: 0.52 m² | 5.6 ft²

Sterilization
G-: γ-irradiatable
--: autoclavable

Connector Inlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
F: ¾" tri-clamp 25 mm
H: ¼" multiple stepped hose barb (only size 7 with filling bell)

Connector Outlet
S: 1½" tri-clamp 50.5 mm
O: ½" single stepped hose barb
F: ¾" tri-clamp 25 mm
H: ¼" multiple stepped hose barb (only size 7 with filling bell)

Packing Size
A: box of 4 (size 7, 8, 9)
V: box of 2 (size 0)

Capsules | Gamma Capsules

549	13	07	H	4	■	■	■	--	B

Filter Size
4: 0.021 m² | 0.22 ft²

Sterilization
G-: γ-irradiatable
--: autoclavable

Connector Inlet
S: ¾" tri-clamp 25 mm
O: ¼" multiple stepped hose barb

Connector Outlet
S: ¾" tri-clamp 25 mm
O: ¼" multiple stepped hose barb

Packing Size
B: box of 5

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