SARTORIUS

Product Datasheet

Sartobind® Cassettes, 4 and 8 mm Bed Height

Process-Scale Membrane Adsorbers

Benefits

- Simple pod-like modular cassette system up to 100 L bed volume
- Flexible and modular system fits exactly to needed capacity
- Disposable or batch-reusable
- Directly scalable from a small capsule
- Designed for capture chromatography of virus vaccines, virus like particles (VLP), large proteins such as blood factors and conjugated proteins, glycoproteins, antibody drug conjugates (ADCs) as well as for flow-through polishing at largest scale
- Q anion exchanger also available in validated gamma-sterile version

γ-irradiated

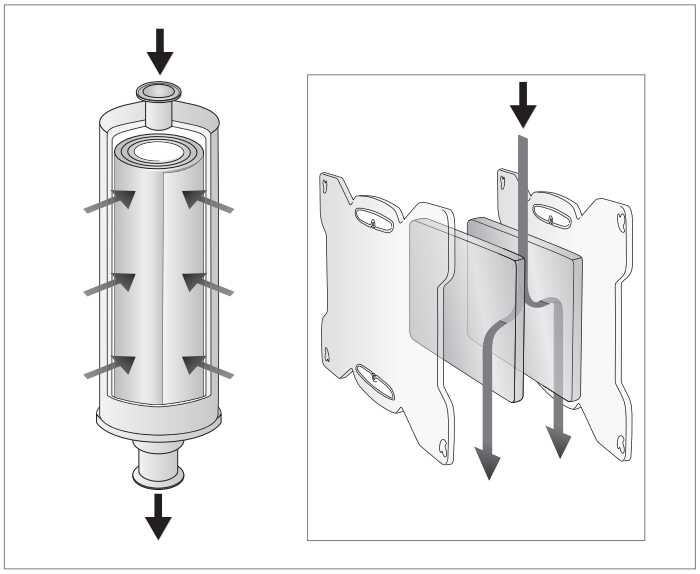
Product Information

Membrane chromatography was limited by size to 5 L membrane volume for almost a decade ignoring the needs for bind and elute chromatography. As capture of large proteins (such as blood factors, conjugated proteins or viruses and virus like particles) plays an increasing role, a new modular pod-like format is developed. The design is derived from the 4 | 8 mm Sartobind capsules to keep the flow path, bed heights, void volumes and last but not least the membrane types constant. A multiple number of cassettes can be quickly set up in a holder to get the exact volume needed. As a result the cassettes can be directly scaled from a smaller capsule size and pressure flow relation, shape of breakthrough curves and binding capacities per volume are independent of the number of cassettes applied.

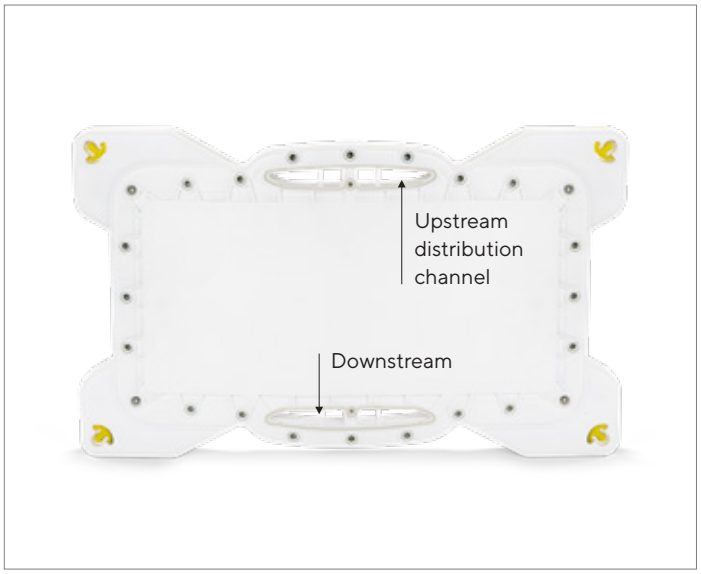
The same Sartobind membranes are incorporated in the cassettes as in the capsules to be used for large scale capturing and impurity removal at high flow rates. Sartobind strong anion (Q) and cation (S) ligands are covalently attached on a flexible hydrogel onto the stabilized reinforced cellulose. For Sartobind STIC® PA (primary amine) salt tolerant anion exchanger and Sartobind Phenyl hydrophobic interaction chromatography (HIC) adsorber, ligands are directly attached to the matrix. The membrane pore size of >3 µm allows large proteins, bioparticles and viruses to enter the macroporous structure and achieves high binding capacity without size exclusion effects.
The membrane is stacked to a bed height of 4 mm (0.8 L) or 8 mm (1.6 L) in a pod-like cassette setup.

If capture or polishing needs to be run under sterile conditions, Sartobind Q cassettes are the device of choice, as they can be delivered also gamma-irradiated and with validated sterility. Two applications that could especially benefit are virus purification processes that cannot be sterile filtered prior to filling due to the virus size, and continuous manufacturing operations that run over a prolonged period of time. Sterile Q cassettes fulfill all the same specifications as the non-sterile versions.

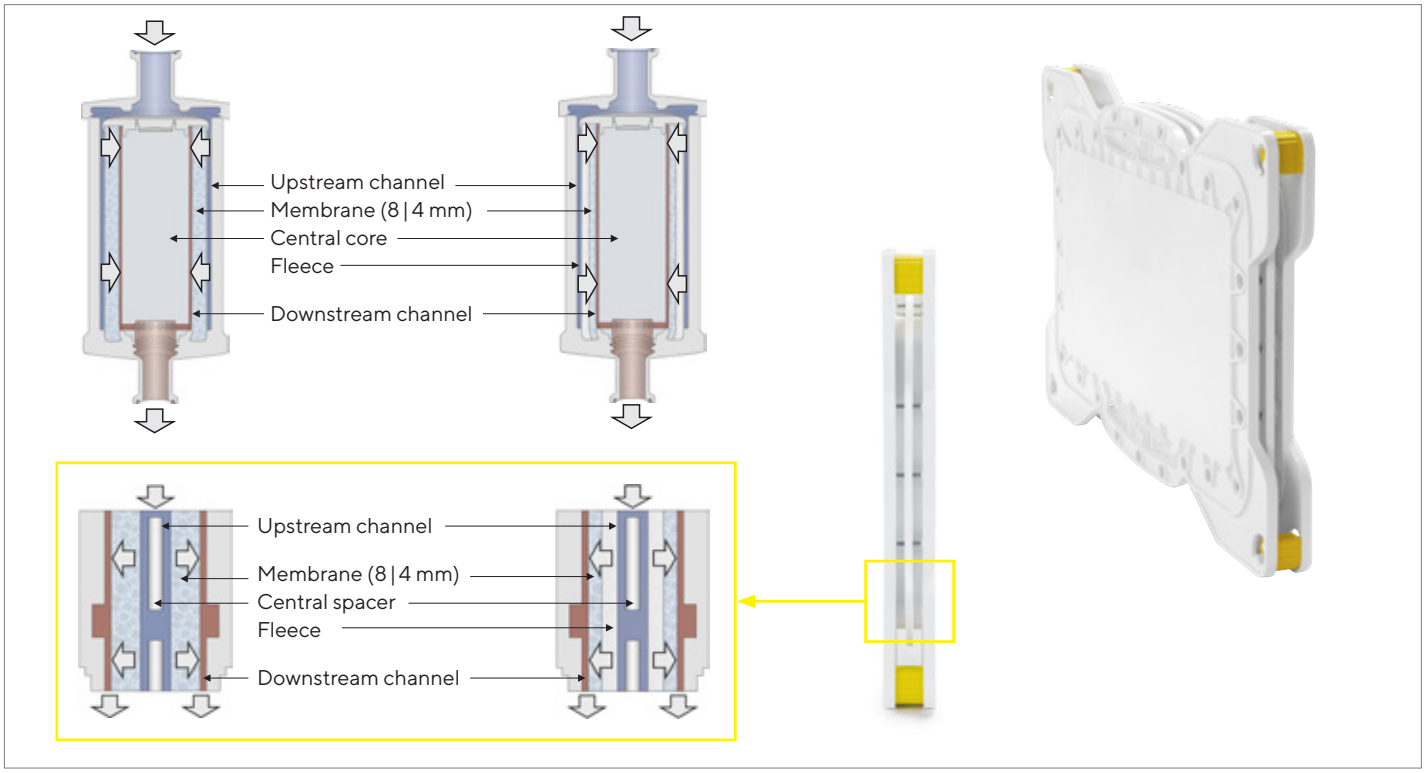
Cassette Design



The cassette design is directly derived from the Sartobind capsules. Cutting and unrolling the membrane stacks results in two membrane stacks of 4 or 8 mm bed height. To achieve a small footprint, the stacks are unrolled.
The feed enters between the membrane stack separated by a central spacer, flows through the membrane stacks and is collected at both sides of the outlet.

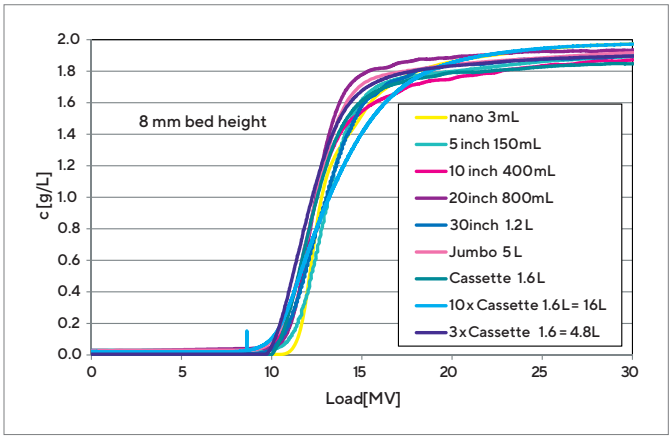


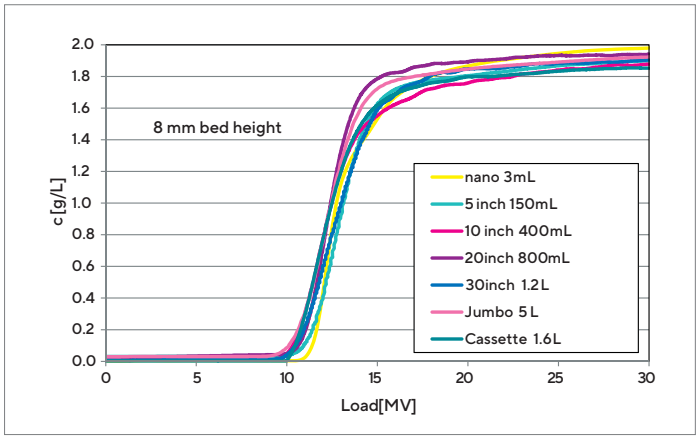
The side view of the cassette displays the upstream distribution channel where the feed enters between the two membrane stacks. The lower downstream channel collects the outlet of each cassette.



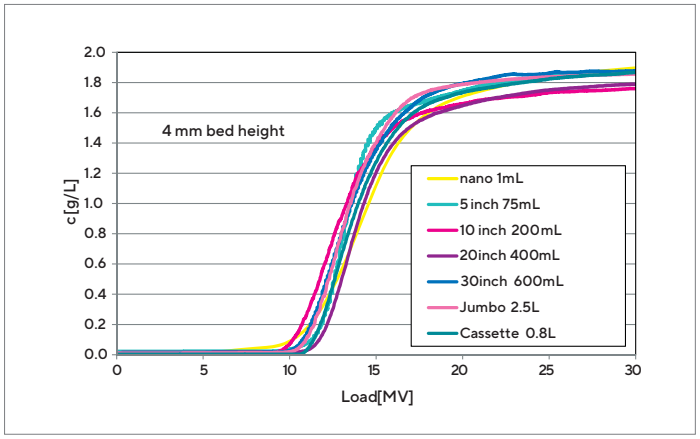
The direct comparison of capsule (upper cutaway) and cassette design (bottom) shows same construction principles, bed height and flow scheme.

Breakthrough Curve and Pressure Flow Comparison to Capsules

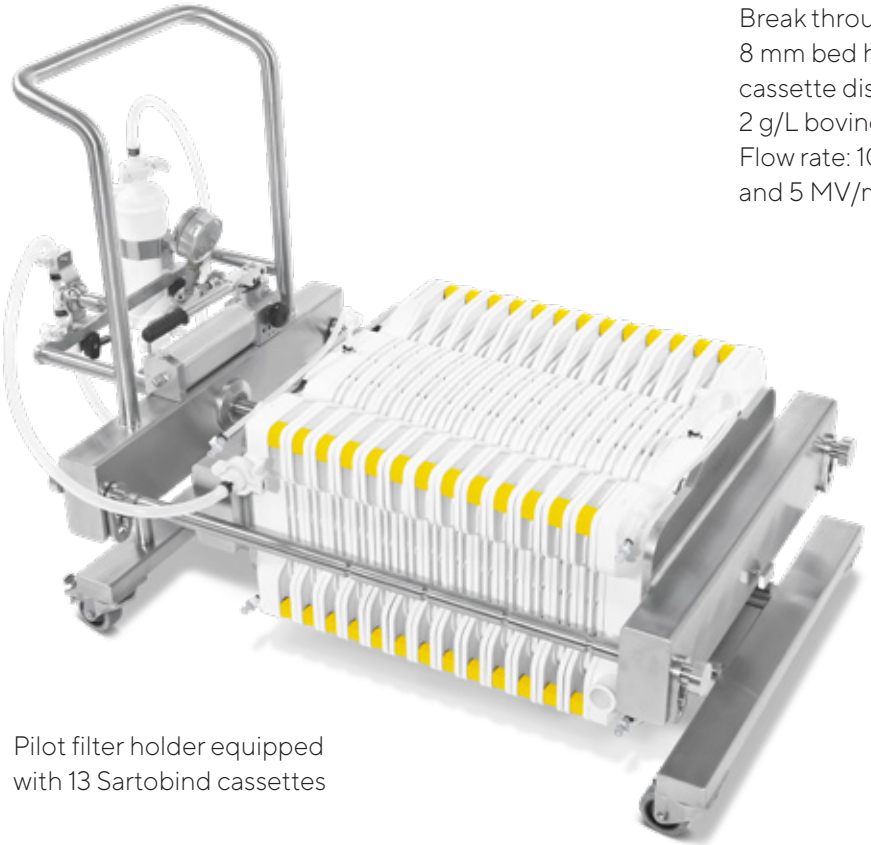




Sartobind devices 8 mm bed height from nano to Jumbo capsules are compared to 3 x and 10 x cassettes and display same breakthrough behavior. Sample: 2 g/L bovine serum albumin in Tris HCl, pH 7.2, 20 mM NaCl. Flow rate: 5 MV/min.



Break through curves of Sartobind devices with 4 mm and 8 mm bed height from nano to Jumbo capsules and cassette display same breakthrough curve. Sample: 2 g/L bovine serum albumin in Tris HCl, pH 7.2, 20 mM NaCl. Flow rate: 10 membrane volumes (MV) per minute in 4 mm and 5 MV/min in 8 mm devices



Pilot filter holder equipped with 13 Sartobind cassettes

Capture

- Viruses (e.g. adeno- or lentivirus)
- Virus like particles (VLP)
- Large proteins such as blood factors
- Q can be delivered in a sterile cassette version if terminal sterile filtration is not possible

Polishing

- Host cell proteins
- DNA and viruses
- Aggregates
- Endotoxins

Technical Data

Specifications

Membrane materials	
Matrix	Stabilized reinforced cellulose
Membrane thickness | membrane volume = membrane area	275 µm | 1 mL = 36.4 cm^2
Nominal pore size	> 3 µm
Ion exchanger ligand Q	Strong anion Q: quaternary ammonium ($R\text{-}CH_2\text{-}N^+(CH_3)_3$)
Ion exchanger ligand STIC PA	Weak anion STIC PA: primary amine ($R\text{-}NH_2$)
Ion exchanger ligand S	Strong cation S: sulfonic acid ($R\text{-}CH_2\text{-}SO_3^-$)
Hydrophobic interaction ligand	HIC: Phenyl ($R\text{-}NH\text{-}C_6H_5$)

Cassette materials	
Outer cage, seal, nonwoven, fleece	ABS, silicone, polyethylene

Operation	
Depyrogenation	1 N NaOH for 30 minutes at 20°C
Integrity testing	By the diffusion test method with Sartocheck® 4 Plus

Typical dynamic binding capacity at 10% breakthrough	
Q (bovine serum albumin, 20 mM Tris/HCl, pH 7.5)	29 mg/mL (0.8 mg/cm^2)
STIC PA (BSA, 20 mM Tris HC, 150 mM NaCl, pH 7.5)	50 mg/mL (1.4 mg/cm^2)
STIC PA (salmon sperm DNA, 20 mM Tris/HCl, 150 mM NaCl pH 7.2)	10.9 mg/mL (0.3 mg/cm^2)
S (lysozyme, 10 mM potassium phosphate, pH 7.0)	25 mg/mL (0.7 mg/cm^2)
Phenyl (polyclonal bovine IgG, 50 mM potassium phosphat, 0.9 M $(NH_4)_2SO_4$, pH 7.5)	14.6 mg/mL (0.4 mg/cm^2)

Ligand density	
Q	2 – 5 µeq/cm^2
STIC PA	18 – 22 µeq/cm^2
S	2 – 5 µeq/cm^2
Phenyl	3 µeq/cm^2

pH stabilities	Short term	Long term
Q	pH 1 – 14	pH 2 – 12
STIC PA	pH 2 – 14	not defined
S	pH 3 – 14	pH 4 – 13
Phenyl	pH 2 – 14	pH 3 – 13

Gamma irradiated products	Gamma dose	Sterile validated
Sterile Sartobind Q cassettes 4 mm and 8 mm	≥ 25 kiloGrays (kGy) maximum dose: 50 kGy	Yes, minimum dose for sterility is 7–8 kGy
Gamma irraditated manifold	See above	No

Dimensions and Connections

Membrane volume | 4 mm	**1 mL**	**75 mL**	**200 mL**	**400 mL**	**600 mL**	**2,500 mL**	**800 mL**
Membrane volume | 8 mm	**3 mL**	**150 mL**	**400 mL**	**800 mL**	**1,200 mL**	**5,000 mL**	**1,600 mL**
Size	**Nano**	**5″**	**10″**	**20″**	**30″**	**Jumbo**	**Cassette**

Membrane area cm^2 | 4 mm	36.4	2,700	7,300	14,600	22,000	91,000	29,000*
Membrane area cm^2 | 8 mm	110	5,500	14,600	29,000	44,000	182,000	58,000*
Void volume mL MV** | 4 mm	3.5 | 3.5	2.7 | 200	2.7 | 540	2.7 | 1,080	2.7 | 1,600	2.8 | 7,000	3.1 | 2500*
Void volume mL MV** | 8 mm	1.3 | 4	1.3 | 200	1.4 | 540	1.4 | 1,080	1.3 | 1,600	1.4 | 7,000	1.8 | 2900*
Dimensions one device (height × diameter) mm	37 × 33 h × Ø	190 × 77 h × Ø	350 × 100 h × Ø	570 × 100 h × Ø	810 × 100 h × Ø	850 × 302 h × Ø	634 × 387 × 49 w × h × t
Connectors	Luer female	Sanitary ¾″ 25 mm outer, 14 mm inner diameter	Sanitary 1½″ 50.5 mm outer, 36 mm inner diameter	Sanitary 1½″ 50.5 mm outer, 36 mm inner diameter	Sanitary 1½″ 50.5 mm outer, 36 mm inner diameter	Sanitary 1½″ 50.5 mm outer, 36 mm inner diameter	Sanitary 1½″ 50.5 mm outer, 36 mm inner diameter via manifolds (accessory)
Hose barb version (height × diameter) mm	n.a.	203 × 77	n.a.	n.a.	n.a.	n.a.	n.a.
Approximate weight	10 g	400 g	760 g	1.3 kg	1.9 kg	16 kg 20 kg wet 23 kg filled	4.9 kg* 6.0 kg* wet

n.a. = not available, *Multiply with the number of used cassettes **MV = membrane volume (including the porosity of the membrane which is 80%)

Size | Membrane Volume Options for Cassettes in the Pilot Filter Holder

Number of cassettes	1	2	3	4	5	6	7	8	9	10	11	12	13
Membrane volume L | 4 mm	**0.8**	**1.6**	**2.4**	**3.2**	**4**	**4.8**	**5.6**	**6.4**	**7.2**	**8**	**8.8**	**9.6**	**10.4**
Membrane volume L | 8 mm	**1.6**	**3.2**	**4.8**	**6.4**	**8**	**9.6**	**11.2**	**12.8**	**14.4**	**16**	**17.6**	**19.2**	**20.8**
Membrane area 4 mm. m^2	2.9	5.8	8.7	11.6	14.5	17.4	20.3	23.2	26.1	29.0	31.9	34.8	37.7
Membrane area 8 mm. m^2	5.8	11.6	17.4	23.2	29.0	34.8	40.6	46.4	52.2	58.0	63.8	69.6	75.4
Void volume 4 mm. L	2.5	5.0	7.5	10.0	12.5	15.0	17.5	20.0	22.5	25.0	27.5	30.0	32.5
Void volume 8 mm. L	2.9	5.8	8.7	11.6	14.5	17.4	20.3	23.2	26.1	29.0	31.9	34.8	37.7
Approximate weight kg	4.9	9.8	14.7	19.6	24.5	29.4	34.3	39.2	44.1	49	53.9	58.8	63.7
Approximate weight wet kg	6	12	18	24	30	36	42	48	54	60	66	72	78
Weight of manifold set. 1 in | 1 out kg	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2	11.2
Weight Pilot Filter Holder kg	160	160	160	160	160	160	160	160	160	160	160	160	160
Total weight kg	176	181	186	191	196	201	206	210	215	220	225	230	235
Total weight wet kg	182	193	204	215	226	237	248	258	269	280	291	302	313

Size of the Pilot Filter Holder for all configurations: 1327 × 955 × 790 mm (w × h × d)

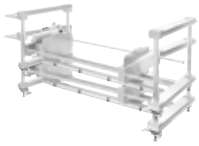
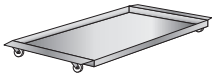
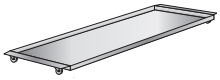
Ordering Information

Sartobind Cassettes

Order number	Description	Quantity	Bed height [mm]	Protein binding capacity [g]	Recommended flow rate [L/min]	Maximum pressure [MPa] (bar | psig)
Sartobind Q						
98IEXQ42D-L	Sartobind Q Cassette 0.8 L, 4 mm, 1½" sanitary clamp via manifold set (accessory), manual, certificate	1	4	23.2	16	0.2 (2 | 29)
98IEXQ42E-P	Sartobind Q Cassette 1.6 L, 8 mm,1½" sanitary clamp via manifold set (accessory), manual, certificate	1	8	46.4	8	0.2 (2 | 29)
98IEXQ42DGL	Sartobind Q Cassette 0.8 L, 4 mm, sterile by gamma irradiation at ≥ 25 kGy, max.50 kGy, 1½" sanitary clamp via gamma manifold set (accessory), manual, certificate	1	4	23.2	16	0.2 (2 | 29)
98IEXQ42EGP	Sartobind Q Cassette 1.6 L, 8 mm, sterile by gamma irradiation at ≥ 25 kGy, max.50 kGy, 1½" sanitary clamp via gamma manifold set (accessory), manual, certificate	1	8	46.4	8	0.2 (2 | 29)

Order number	Description	Quantity	Bed height [mm]	Protein binding capacity [g]	Recommended flow rate [L/min]	Maximum pressure [MPa] (bar | psig)
Sartobind S						
98IEXS42D-L	Sartobind S Cassette 0.8 L, 4 mm, 1½" sanitary clamp via manifold set (accessory), manual, certificate	1	4	20.3	16	0.2 (2 | 29)
98IEXS42E-P	Sartobind S Cassette 1.6 L, 8 mm,1½" sanitary clamp via manifold set (accessory), manual, certificate	1	8	40.6	8	0.2 (2 | 29)
Sartobind STIC PA						
98STPA42D-L	Sartobind STIC PA Cassette 0.8 L, 1½" sanitary clamp via manifold set (accessory), manual, certificate	1	4	40.6	16	0.2 (2 | 29)
Sartobind Phenyl						
98HICP42E-P	Sartobind Phenyl Cassette 1.6 L, 8 mm, 1½" sanitary clamp via manifold set (accessory), manual, certificate	1	8	23.2	8	0.2 (2 | 29)

Accessories

Order number		Description	Quantity
29Z-S00001		Manifold set, 1½" sanitary clamp, inlet and outlet adapter plate	2
29Z-S00003		Gamma irradiated manifold set, 1½" sanitary clamp, inlet and outlet adapter plate, ≥ 25 kGy, max.50 kGy	2
2ZGL--0005		Pilot Filter Holder	1
2ZGL--0006		Process filter holder	1
2ZGL--0007		Double process filter	1
2ZGL--0008		Drip pan for Pilot Filter holder	1
2ZGL--0015		Drip pan for Process and double Process Filter Holder	1
2ZGL--0013		Separation Plate for serial or parallel fluid distribution	1
2ZGL--0014		Pressure Safety Device, to prevent excessive pressure during compressed air draining of the cassettes	1
26787---FT---P		Sartocheck® 5 Plus Filter Integrity Tester	1

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

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com

DIR No.: 2642993-000-00
Order No.: 85037-557-43
Status: 10 | 2020