EverLUX®

0.4 µm SMH-grade Mini Capsule Filter (CM2/CK2 Model)

Description

The EverLUX® SMH0.4 is an advanced, highly asymmetric PES membrane filter that provides high contaminant capacity, extended service life, and high flow rates when filtering a wide range of aqueous and biological liquids. This hydrophilic filter withstands a wide pH range (1-14) and is ideal for bioburden reduction in a range of low-to-high contaminant liquids, including pharmaceutical preparations, biopharmaceuticals, parenterals, vaccines, complex biologicals, serum, cell and tissue culture media additives, supernatants, process intermediate, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols, and sanitizing agents.

Materials of Construction

All components of the EverLUX® filter capsule are animal component free. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Filter membranes:	Polyethersulfone (PES)	CFR Title 21, 177.2440
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.4 µm

Minimum Bubble Point 40 psi (2.8 bar), water

Bacterial Retention >10^7 per cm^2 removal of *Serratia marcescens* per modified ASTM F838

Operating Characteristics

Operating temperature range:	32 °F to 122 °F (0 °C to 50 °C)
Maximum temperature rating:	160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure:	100 psig @ 122 °F (6.9 bar @ 50 °C)
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles. Water wet membrane prior to autoclaving.
Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety

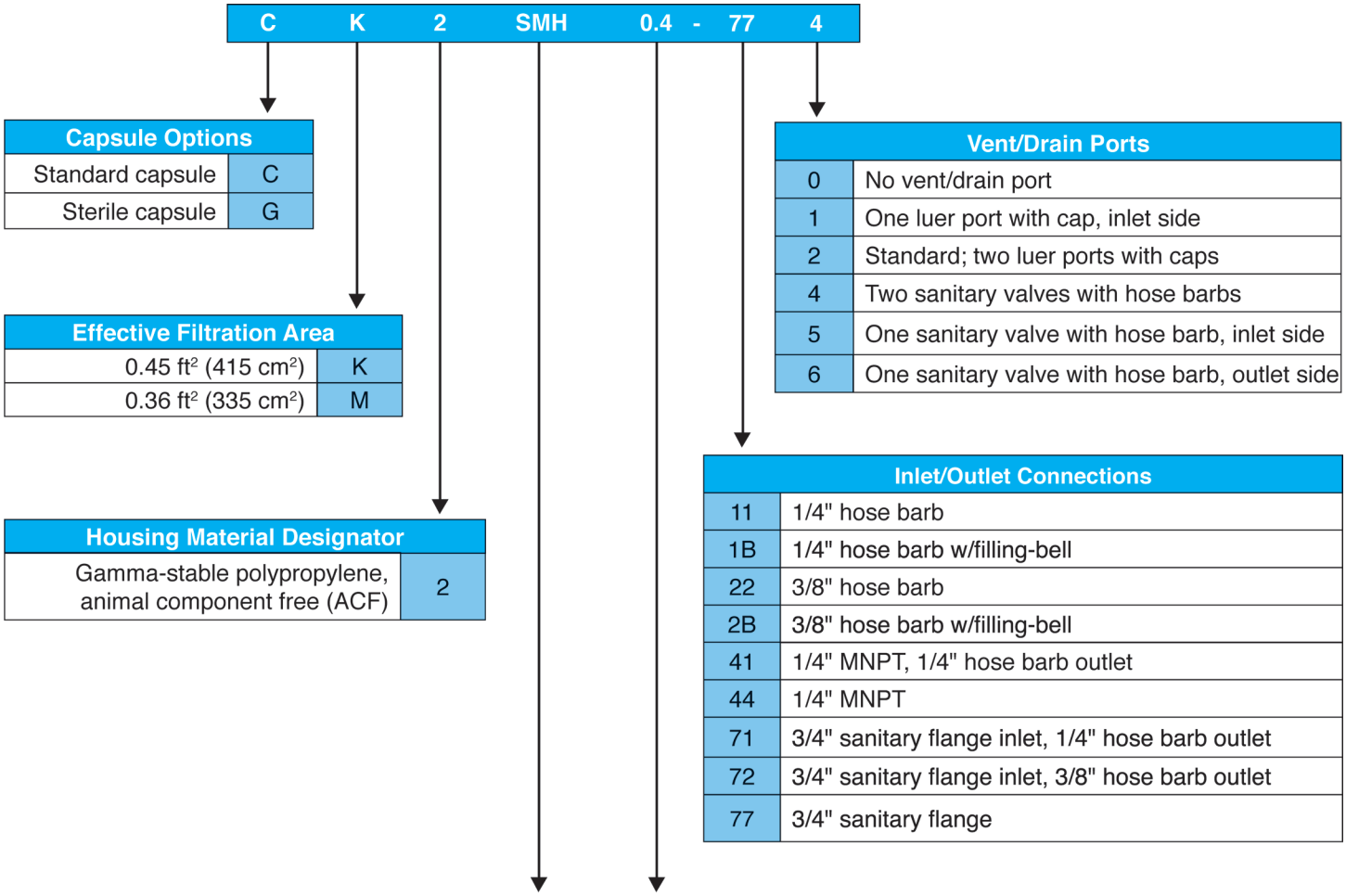
EverLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of EverLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> *Limulus* amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of EverLUX® filters. Filters comply with European Commission Regulation (EU) No 10/2011. EverLUX® CM2/CK2 capsules are TSE/BSE/animal component free.

Quality Assurance

EverLUX® filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each EverLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.

MEISSNER

Ordering Guide



Capsule Options	
Standard capsule	C
Sterile capsule	G

Effective Filtration Area	
0.45 ft² (415 cm²)	K
0.36 ft² (335 cm²)	M

Housing Material Designator	
Gamma-stable polypropylene, animal component free (ACF)	2

Vent/Drain Ports	
0	No vent/drain port
1	One luer port with cap, inlet side
2	Standard; two luer ports with caps
4	Two sanitary valves with hose barbs
5	One sanitary valve with hose barb, inlet side
6	One sanitary valve with hose barb, outlet side

Inlet/Outlet Connections	
11	1/4" hose barb
1B	1/4" hose barb w/filling-bell
22	3/8" hose barb
2B	3/8" hose barb w/filling-bell
41	1/4" MNPT, 1/4" hose barb outlet
44	1/4" MNPT
71	3/4" sanitary flange inlet, 1/4" hose barb outlet
72	3/4" sanitary flange inlet, 3/8" hose barb outlet
77	3/4" sanitary flange

Product	Grade	Retention Rating
EverLUX® hydrophilic PES membrane	SMH	0.4 µm

Additional information about this filter product is available in the EverLUX® Green Docs document at www.meissner.com/green-docs.

MEISSNER
1001 Flynn Road • Camarillo, CA 93012 • USA
+1.805.388.9911 • +1.805.388.5948 Fax
www.meissner.com