

SteriLUX®

0.4 µm VMH-grade Large Capsule Filter (UltraCap® H.D. Model)

Description

The SteriLUX® VMH0.4 capsule filter is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols, and sanitizing agents.

Materials of Construction

All components of the filter are either animal component free (ACF) or in compliance with EMA/410/01 Rev. 3 (EDQM 5.2.807/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane:	Polyvinylidene fluoride (PVDF)	CFR Title 21, 177. 2510
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 shell:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.4 µm

Effective Filtration Area 7.9 ft² (0.73 m²) per 10"

Minimum Bubble Point
28 psi (1.93 bar), water
10 psi (0.69 bar) 60% IPA/40% water
9 psi (0.62 bar) 70% IPA/30% water

Maximum Diffusion Rate 15 mL/min per 10" (25 cm) @ 22 psi (1.52 bar), water

Bacterial Retention >10⁷ cfu per cm² removal of *Serratia marcescens* per modified ASTM F838

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum Temperature rating:	140 °F @ 55 psig (60 °C @ 3.8 bar) liquid, @ 35 psig (2.4 bar) gas
Maximum operating pressure:	90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
Maximum operating pressure:	60 psig @ 100 °F (4.1 bar @ 38 °C), gas service
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles.

Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

Biological Safety

SteriLUX® 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 SteriLUX® filters are less than 0.5 EU/mL, as determined using the *Limulus* amoebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of SteriLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011.

Quality Assurance

SteriLUX® 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 SteriLUX® filter is clearly marked with filter type, lot number, and serial number.

Ordering Guide

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Sterile Filter Options	
Standard capsule	CR
Sterile capsule	GR

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

Vent/Drain Ports	
Inline Configuration	
0	No vents/drains
2	Vent/drain at inlet and outlet
4	Vent/drain valve at outlet
K	SPD vent/drain at inlet and outlet
L	SPD vent/drain at outlet
T-Style Configuration	
0	No vent; no drain
1	No vent; standard 1/4" drain plug
2	Standard vent valve; standard drain plug
3	Standard vent valve & drain plug; 3/4" sanitary gage port
4	Standard vent valve; no drain
5	Standard vent valve; no drain; gage port
6	No vent; no drain; gage port
A	No vent; sanitary drain valve
B	Standard vent; sanitary drain valve
C	Standard vent; sanitary drain valve; gage port

Inlet/Outlet Connections			
00	1" sanitary flange	77	3/4" sanitary flange
02	1" sanitary flange in & 3/8" hose barb out	88	3/4" hose barb
08	1" sanitary flange in & 3/4" hose barb out	99	9/16" hose barb
09	1" sanitary flange in & 9/16" hose barb out	AA	1/2" male Flaretek®
0C	1" sanitary flange in & 1/2" hose barb out	BB	3/4" male Flaretek®
0D	1" sanitary flange in & 1" hose barb out	CC	1/2" hose barb
22	3/8" hose barb	DD	1" hose barb

Body Style	
N	Inline configuration
T	T-style configuration

Filter Length									
1	10"	2	20"	3	30"	4	40"	5	50"

Product	Grade	Pore Size
SteriLUX® hydrophilic PVDF membrane	VMH	0.4 µm

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

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