

# SteriLUX®

## 0.4 µm VTH-grade Large Capsule Filter (UltraCap® Model)

### Description

The SteriLUX® VTH0.4 capsule filter is a hydrophilic PVDF membrane filter with low protein binding properties and broad chemical compatibility. It is recommended for sterile filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, and ophthalmic and other dilute preservative solutions.

The filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology, and related industries.

### 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 ft<sup>2</sup> (0.73 m<sup>2</sup>) 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** >10<sup>7</sup> cfu per cm<sup>2</sup> 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 @ 45 psig (60 °C @ 3.1 bar) liquid, @ 30 psig (2.1 bar) gas
Maximum operating pressure:	75 psig @ 100 °F (5.2 bar @ 38 °C), liquid
Maximum operating pressure:	50 psig @ 100 °F (3.4 bar @ 38 °C), gas
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® VTH0.4 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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 integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.

**Ordering Guide**

**CU VTH 0.4 - 1 T 88 4**

Sterile Filter Options	
Standard	CU
Presterilized	GU

Vent/Drain Ports	
Inline Configuration	
0	No vents/drains
2	Vent/drain at inlet and outlet
4	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 & drain plug; 3/4" sanitary gage port
4	Standard vent; no drain
5	Standard vent; no drain; gage port
6	No vent; no drain; gage port

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

Body Style			
N	Inline configuration	T	T-style configuration

Filter Length					
1	10"	2	20"	3	30"

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

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

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