SteriLUX®

VMH0.4 Capsule

Description

The SteriLUX® VMH grade 0.4 µm PVDF hydrophilic filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

Materials of Construction

All components of the SteriLUX® filter capsule are either animal free or in compliance with EMEA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), 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	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 housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.4 µm

Minimum Bubble Point 28 psi (1,9 bar), water

Maximum Diffusion Rate

1.6 ft^2: 4.0 mL/min @ 22 psi (1,5 bar), water
3.3 ft^2: 6.4 mL/min @ 22 psi (1,5 bar), water

Bacterial Retention >10^7 per cm^2 removal of *Serratia marcescens* per modified ASTM F838-05

Operating Characteristics

Operating temperature range: 32 ºF to 100 ºF (0 °C to 38 °C)
Maximum temperature rating: 160 ºF @ 35 psig (72 °C @ 2,4 bar)
Maximum operating pressure (liquid service): 75 psig @ 100 ºF (5,2 bar @ 38 ºC)
Maximum operating pressure (gas service): 50 psig @ 100 ºF (3,4 bar @ 38 ºC)

Sterilization

Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be steamed in place (SIP).

Biological Safety

SteriLUX® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of SteriLUX® filters are less than 0.5 EU/mL, as determined using the *Limulus* amebocyte 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 integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

MEISSNER FILTRATION PRODUCTS

Ordering Guide

Capsule Options	
Standard capsule	C
Sterile capsule	G
Opaque shell	O

Effective Filtration Area (nominal)	
3.3 ft² (0,31 m²)	L
1.6 ft² (0,15 m²)	S

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

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

Inlet / Outlet Connections			
00	1" sanitary (TC) flange	44	1/4" MNPT
02	1" TC in; 3/8" hose barb out	55	3/8" FNPT
0C	1" TC in; 1/2" hose barb out	66	3/8" MNPT
CC	1/2" hose barb (rigid tubing)	77	3/4" sanitary (TC) flange
22	3/8" hose barb	88	3/4" hose barb
2B	3/8" hose barb w/filling-bell	99	1/2" hose barb (flexible tubing)

Product	Filter Grade	Retention Rating
SteriLUX® hydrophilic PVDF membrane	VMH	0.4

Additional information about SteriLUX® filter products is available in the Green Docs document which is viewable at https://www.meissner.com/downloads/sterilux-gd003-2.1.pdf

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