SteriLUX®

0.1 µm VTH-grade Small Filter Cartridge (L Model)

Description

SteriLUX® is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for sterilizing filtration and mycoplasma removal 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.

The SteriLUX® VTH0.1 filter cartridge 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 SteriLUX® VTH0.1 filter cartridge 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
O-rings:	Typically silicone	CFR Title 21, 177.2600
Sealing method:	Thermal bonding	

Pore Size	0.1 µm
Minimum Bubble Point	70 psi (4.8 bar), water 26 psi (1.8 bar) 60% IPA/40% water 25 psi (1.7 bar) 70% IPA/30% water
Maximum Diffusion Rate	1.6 ft^2 (0.15 m^2): 4.0 mL/min @ 56 psi (3.86 bar), water 3.3 ft^2 (0.31 m^2): 8.5 mL/min @ 56 psi (3.86 bar), water
Typical Water Flow Rate	2.9 psid/gpm per 5" (0.19 L/min at Δp 10 mbar per 13 cm)
Bacterial Retention	>10^7 per cm^2 removal of *Brevundimonas dimuta* per ASTM F838

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	180 °F @ 30 psid (82 °C @ 2.1 bar)
Maximum operating pressure:	80 psid @ 100 °F (5.5 bar @ 38 °C)
Maximum reverse pressure:	15 psid @ 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.
Steam-in-place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

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* 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.

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Quality Assurance

A Certificate of Quality is supplied for SteriLUX® filters 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 and lot number.

Ordering Guide

L	VTH	0.1	-	2	P	R	S

Model	
Small Flow Element (SFE)	L

O-ring Seal Material	
B	Buna
E	EPR
S	Silicone
T	Teflon® over Silicone
V	Viton®
X	Teflon® over Viton®

Reinforcement Ring Option	
(blank)	Standard - no reinforcement ring
R	Reinforcement ring - required only for the 222 and 226 adapter when autoclaving or steam sterilizing

Cartridge Configuration	
P	SOE, internal 116 O-ring, button cap end
2	SOE, 222 O-rings, button cap end
6	SOE, 226 O-rings, button cap end
SK	SOE, Skirt-flange adapter
L	116 O-ring with mini lock

Cartridge Length			
2	2.5" (7 cm)	5	5.0" (13 cm)

Product	Grade	Pore Size
SteriLUX® hydrophilic PVDF membrane	VTH	0.1 µm

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

MEISSNER
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