SteriLUX®

VTH0.1 Cartridge

Description

SteriLUX® is 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 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.

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

Pore Size

0.1 µm (sterilizing grade)

Typical Water Flow Rate

1.5 psid/gpm per 10" (0.4 L min^{-1} at Δp 10 mbar per 25 cm)

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

20 mL/min per 10" (25 cm) @ 56 psi (3.86 bar), water Air
18 mL/min per 10" (25 cm) @ 56 psi (3.86 bar), water Nitrogen

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)

Bacterial Retention

>10^7 per cm^2 removal of *Brevundimonas diminuta* per ASTM F838

Sterilization

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

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.

MEISSNER FILTRATION PRODUCTS

Quality Assurance

Each SteriLUX® VTH0.1 is 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 and lot number.

Ordering Guide

VTH	0.1	-	1	F6	R	S

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 for autoclave/SIP applications

Cartridge Configuration	
C2	SOE, 222 O-rings, button cap end
C6	SOE, 226 O-rings, button cap end
F2	SOE, 222 O-rings, fin end
F6	SOE, 226 O-rings, fin end

Cartridge Length							
1	10"	2	20"	3	30"	4	40"

Filter Code	Retention Rating
VTH	0.1

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

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