

SteriLUX®

VMH0.4 Small Flow Element

Description

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

Materials of Construction

All components of the SteriLUX® filter cartridge 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 0.4 µm

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

Maximum Diffusion Rate
1.6 ft² (0,15 m²): 3.0 mL/min @ 22 psi (1,51 bar), water
3.3 ft² (0,31 m²): 6.4 mL/min @ 22 psi (1,51 bar), water

Typical Water Flow Rate 0.56 psid/gpm per 5" (1,0 L/min at Δp 10 mbar per 13 cm)

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

Operating Characteristics

100 °F @ 80 psid (38 °C @ Δp 5,5 bar)	150 °F @ 60 psid (66 °C @ Δp 4,1 bar)	180 °F @ 30 psid (82 °C @ Δp 2,1 bar)
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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* 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 integrity tested during manufacture and is clearly marked with filter type and lot number.

