SteriLUX®

0.2 μm VMH-grade Filter Cartridge

Description
The SteriLUX® VMH0.2 is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for filtration 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.

Materials of Construction
All components of the SteriLUX® filter cartridge are either animal component free (ACF) 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 (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/gaskets: Typically silicone CFR Title 21, 177.2600
- Sealing method: Thermal bonding

Pore Size
0.2 μm

Minimum Bubble Point
- 50 psi (3.44 bar), water
- 18 psi (1.24 bar), 60% IPA/40% water
- 17 psi (1.17 bar), 70% IPA/30% water

Maximum Diffusion Rate
13.5 mL/min per 10" @ 40 psi, water (13.5 mL/min per 25 cm @ 2.76 bar, water)

Typical Water Flow Rate
0.75 psid/gpm per 10" (0.73 L/min at Δp 10 mbar per 25 cm)

Bacterial Retention
>10⁷ per cm² removal of Brevundimonas diminuta per ASTM F838

Operating Characteristics
- Operating temperature range: 32 °F to 180 °F (0 °C to 82 °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.

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 clearly marked with filter type and lot number.
Ordering Guide

**GS option is only available for 9.75", 19.5", 29.25", and 39" length filters.**

**GL option is only available for 20", 30", and 40" length filters.**

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

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