SteriLUX®

0.2 μm VTH-grade Small Filter Cartridge (L model)

Description
SteriLUX® VTH0.2 is a hydrophilic PVDF membrane filter with low protein binding properties and broad chemical compatibility. It is recommended for sterile 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® VTH0.2 small filter cartridge, or small flow element (SFE), 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 component 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 (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
0.2 μm

Minimum Bubble Point
50 psi (3.44 bar), water
18 psi (1.24 bar), 60% IPA/40% water

Maximum Diffusion Rate
2.5” (7 cm): 2.7 mL/min @ 40 psi (2.76 bar), water
5.0” (13 cm): 5.7 mL/min @ 40 psi (2.76 bar), water

Typical Water Flow Rate
2.5” (7 cm): 3.40 psid/gpm (0.16 L/min @ Δp 10 mbar)
5.0” (13 cm): 1.62 psid/gpm (0.34 L/min @ Δp 10 mbar)

NVR Extractables
≤ 0.05 %

Bacterial Retention
>10⁷ per cm² removal of Brevundimonas diminuta 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.
- In-line steam sterilized: 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, physicochemical, oxidizable substances, and USP <87> cytotoxicity. 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 USP <85>. No binders, adhesives, or surfactants are used in the construction of SteriLUX® filters. Filters comply with European Commission Regulation No 10/2011.

MEISSNER FILTRATION PRODUCTS
Quality Assurance
Each SteriLUX® VTH0.2 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

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<th>Model</th>
<th>Grade</th>
<th>Pore Size</th>
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<tr>
<td>Small Flow Element</td>
<td>VTH</td>
<td>0.2 μm</td>
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Additional information about this filter product is available in the SteriLUX® Green Docs document at www.meissner.com/green-docs.

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