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 or in compliance with EMEA/410/01 Rev. 3 (EDOM 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>CFR Title(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane:</td>
<td>21, 177.2510</td>
</tr>
<tr>
<td>Upstream support:</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Downstream support:</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Outer guard:</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Core:</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>End caps:</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>O-rings:</td>
<td>自然而硅橡胶</td>
</tr>
<tr>
<td>Sealing method:</td>
<td>热压粘接</td>
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</tbody>
</table>

**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 ft² (0.15 m²): 4.0 mL/min @ 56 psi (3.86 bar), water
- 3.3 ft² (0.31 m²): 8.5 mL/min @ 56 psi (3.86 bar), water

**Typical Water Flow Rate**
2.9 psid/gpm per 5" (0.19 L/min per Δp 10 mbar per 13 cm)

**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.
- 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**

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**

<table>
<thead>
<tr>
<th>Model</th>
<th>L VTH 0.1 - 2 P R S</th>
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</thead>
<tbody>
<tr>
<td>Small Flow Element (SFE)</td>
<td>L</td>
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</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Pore Size</th>
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<tr>
<td>SteriLUX® hydrophilic PVDF membrane</td>
<td>VTH 0.1 μm</td>
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</table>

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

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