SteriLUX®

0.2 µm VTH-grade Standard Capsule Filter (CS/CL Model)

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® VTH0.2 filter capsule 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 capsule 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 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
Capsule housing: Polypropylene CFR Title 21, 177.1520
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
CS: 2.7 mL/min @ 40 psi (2.76 bar), water
CL: 5.7 mL/min @ 40 psi (2.76 bar), water

Bacterial Retention
>10^7 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: 160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
Maximum operating pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas service
Reverse operating pressure: 15 psig @ 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.
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety
SteriLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> 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 <USP> 85. No binders, adhesives or surfactants are used in the construction of SteriLUX® filters. Filters comply with European Commission Regulation No 10/2011.
**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, lot number and serial number.

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**Ordering Guide**

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<th>Housing Material Designator</th>
<th>Effective Filtration Area</th>
<th>Inlet/Outlet Connections</th>
<th>Vent/Drain Ports</th>
<th>Grade</th>
<th>Retention Rating</th>
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<tr>
<td>Standard capsule</td>
<td>Standard polypropylene (blank)</td>
<td>3.3 ft² (0.31 m²) L</td>
<td>00 1&quot; sanitary (TC) flange</td>
<td>0 No vent/drain port</td>
<td>VTH</td>
<td>0.2 µm</td>
</tr>
<tr>
<td>Sterile capsule</td>
<td>Gamma-stable polypropylene, animal component free (ACF)</td>
<td>1.6 ft² (0.15 m²) S</td>
<td>02 1&quot; sanitary flange in; 3/8&quot; hose barb out</td>
<td>1 One luer port with cap, outlet side</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Opaque shell</td>
<td></td>
<td></td>
<td>0C 1&quot; sanitary flange in; 1/2&quot; hose barb out</td>
<td>2 Standard; two luer ports with caps</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CC 1/2&quot; hose barb (rigid tubing)</td>
<td>4 Two sanitary valves with hose barbs</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22 3/8&quot; hose barb</td>
<td>5 One sanitary valve with hose barb, outlet side</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2B 3/8&quot; hose barb w/ filling bell</td>
<td>6 One sanitary valve with hose barb, inlet side</td>
<td>1.0</td>
<td></td>
</tr>
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*3/4 sanitary flange fitting option is only available for CS2 and CL2 Capsules.

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

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