**EverLUX®**

0.4 µm SMH-grade Mini Capsule Filter (CM2/CK2 Model)

**Description**
The EverLUX® SMH0.4 is an advanced, highly asymmetric PES membrane filter that provides high contaminant capacity, extended service life, and high flow rates when filtering a wide range of aqueous and biological liquids. This hydrophilic filter withstands a wide pH range (1-14) and is ideal for bioburden reduction in a range of low-to-high contaminant liquids, including pharmaceutical preparations, biopharmaceuticals, parenterals, vaccines, complex biologicals, serum, cell and tissue culture media additives, supernatants, process intermediate, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols, and sanitizing agents.

**Materials of Construction**
All components of the EverLUX® filter capsule are animal component free. 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>Material</th>
<th>CFR Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter membranes</td>
<td>Polyethersulfone (PES)</td>
<td>Title 21, 177.2440</td>
</tr>
<tr>
<td>Upstream support</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Downstream support</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Outer guard</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Core</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>End caps</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Capsule housing</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Sealing method</td>
<td>Thermal bonding</td>
<td></td>
</tr>
</tbody>
</table>

**Pore Size**
0.4 µm

**Minimum Bubble Point**
40 psi (2.8 bar), water

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

**Operating Characteristics**
- Operating temperature range: 32 °F to 122 °F (0 °C to 50 °C)
- Maximum temperature rating: 160 °F @ 35 psig (72 °C @ 2.4 bar)
- Maximum operating pressure: 100 psig @ 122 °F (6.9 bar @ 50 °C)
- Maximum reverse 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. Water wet membrane prior to autoclaving.
- Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
- Capsules must not be in-line steam sterilized.

**Biological Safety**
EverLUX® 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 EverLUX® filters are less than 0.5 EU/mL, as determined using the current USP <85> Limulus amebocyte lysate (LAL) test. No binders, adhesives, or surfactants are used in the construction of EverLUX® filters. Filters comply with European Commission Regulation (EU) No 10/2011. EverLUX® CM2/CK2 capsules are TSE/BSE/animal component free.

**Quality Assurance**
EverLUX® 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 EverLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number, and serial number.
Ordering Guide

Capule Options
- Standard capsule: C
- Sterile capsule: G

Effective Filtration Area
- 0.45 ft² (415 cm²): K
- 0.36 ft² (335 cm²): M

Housing Material Designator
- Gamma-stable polypropylene, animal component free (ACF): 2

Vent/Drain Ports
- 0: No vent/drain port
- 1: One luer port with cap, inlet side
- 2: Standard; two luer ports with caps
- 4: Two sanitary valves with hose barbs
- 5: One sanitary valve with hose barb, inlet side
- 6: One sanitary valve with hose barb, outlet side

Inlet/Outlet Connections
- 11: 1/4" hose barb
- 1B: 1/4" hose barb w/filling-bell
- 22: 3/8" hose barb
- 2B: 3/8" hose barb w/filling-bell
- 41: 1/4" MNPT, 1/4" hose barb outlet
- 44: 1/4" MNPT
- 71: 3/4" sanitary flange inlet, 1/4" hose barb outlet
- 72: 3/4" sanitary flange inlet, 3/8" hose barb outlet
- 77: 3/4" sanitary flange

Product
- EverLUX® hydrophilic
- PES membrane

Grade
- SMH

Retention Rating
- 0.4 μm

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

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