EverLUX®

0.1 µm STC-grade Mini Capsule Filter (CM2/CK2 Model)

Description
The EverLUX® STC0.1 capsule filter features two serially layered PES membranes (one highly asymmetric and one asymmetric) designed for 100% removal of mycoplasma. The coarser upstream layer is optimized for prefiltration. The filter is 100% integrity tested and DI flushed during manufacture, and it has the added benefit of certification that meets the critical needs of the pharmaceutical, biotechnology, and related industries.

Materials of Construction
All components of the filter are animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Membrane: Polyethersulfone (PES) CFR Title 21, 177.2440
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
0.1 µm

Maximum Diffusion Rate
CM2: 1.2 mL/min @ 40 psi (2.76 bar), water
CK2: 1.4 mL/min @ 40 psi (2.76 bar), water

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)

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

Sterilization
Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 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 ameboocyte 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® STC0.1 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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 clearly marked with filter type, lot number, and serial number.
### Ordering Guide

<table>
<thead>
<tr>
<th>Capsule Options</th>
<th>Vent/Drain Ports</th>
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</thead>
<tbody>
<tr>
<td>Standard capsule</td>
<td>0 No vent/drain port</td>
</tr>
<tr>
<td>Sterile capsule</td>
<td>1 One luer port with cap, inlet side</td>
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<thead>
<tr>
<th>Effective Filtration Area</th>
<th>Inlet/Outlet Connections</th>
</tr>
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<tbody>
<tr>
<td>0.35 ft² (325 cm²)</td>
<td>11 1/4” hose barb</td>
</tr>
<tr>
<td>0.28 ft² (260 cm²)</td>
<td>1B 1/4” hose barb with filling bell</td>
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<tr>
<th>Housing Material Designator</th>
<th>22 3/8” hose barb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma-stable polypropylene, animal component free (ACF)</td>
<td>2B 3/8” hose barb with filling bell</td>
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<thead>
<tr>
<th>Product</th>
<th>Grade</th>
<th>Pore Size</th>
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<tr>
<td>EverLUX® hydrophilic PES membrane</td>
<td>STC</td>
<td>0.1 μm</td>
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Additional information about this filter product is available in the EverLUX® Green Docs document at www.meissner.com/green-docs.

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