**EverLUX®**

0.1 µm STC-grade Filter Cartridge

**Description**
The EverLUX® STC0.1 filter cartridge 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 EverLUX® filter cartridge are either animal component free (ACF) 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>Material</th>
<th>CFR Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membranes</td>
<td>Polyethersulfone (PES)</td>
<td>21, 177.2440</td>
</tr>
<tr>
<td>Upstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Downstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Outer guard</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Core</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>End caps</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
</tr>
<tr>
<td>Sealing method</td>
<td>Thermal bonding</td>
<td></td>
</tr>
</tbody>
</table>

**Pore Size**
0.1 µm

**Effective Filtration Area**
6.8 ft² (0.63 m²) per 10”

**Maximum Diffusion Rate**
25 mL/min per 10” (25 cm) @ 40 psi (2.76 bar), water

**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)

**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.
- Steam in place (SIP): 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles. Water wet membrane first.

**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 ameboye 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.

**Quality Assurance**
EverLUX® STC0.1 filter cartridges 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 is clearly marked with filter type and lot number.
Ordering Guide

<table>
<thead>
<tr>
<th>STC</th>
<th>0.1</th>
<th>C2</th>
<th>R</th>
<th>S</th>
</tr>
</thead>
</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 for autoclave/SIP applications

**Cartridge Configuration**
- C2: SOE; 222 O-rings, button cap end
- C6: SOE; 226 O-rings, button cap end
- F2: SOE; 222 O-rings, fin end
- F6: SOE; 226 O-rings, fin end

**Filter Length**
- 1 10”
- 2 20”
- 3 30”
- 4 40”

<table>
<thead>
<tr>
<th>Product</th>
<th>Grade</th>
<th>Pore Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>EverLUX® hydrophilic</td>
<td>STC</td>
<td>0.1 μm</td>
</tr>
<tr>
<td>PES membrane</td>
<td></td>
<td></td>
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</tbody>
</table>

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

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