Description
The STyLUX® SM-grade 0.2 μm is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and 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, and alcohols. The filter’s asymmetric membrane provides absolute retention, while also providing superior flow rates and contaminant capacity.

Materials of Construction
All components of the STyLUX® 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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>CFR Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter Membrane</td>
<td>Polytetrafluoroethylene (Teflon)</td>
<td>21, 176.1900</td>
</tr>
<tr>
<td>Up/Downstream support</td>
<td>Polypropylene</td>
<td>21, 176.1900</td>
</tr>
<tr>
<td>Core, guard, end caps</td>
<td>Polypropylene</td>
<td>21, 176.1900</td>
</tr>
<tr>
<td>Capsule shell</td>
<td>Polypropylene</td>
<td>21, 176.1900</td>
</tr>
<tr>
<td>Sealing Method</td>
<td>Thermal Bonding</td>
<td></td>
</tr>
</tbody>
</table>

Pore Size
0.2 μm

Minimum Bubble Point
44 psi (3.03 bar), water
16 psi (1.10 bar), 60% IPA/40% water
15 psi (1.03 bar), 70% IPA/30% water

Maximum Diffusion Rate
30 mL/min per 10” (25 cm) @ 35 psi (2.41 bar), water

Typical Water Flow Rate
0.3 psid/gpm per 10” (1.8 L/min @ Δp 10 mbar per 25 cm), with 1” (25 mm) inlet/outlet

Operating Characteristics
Operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating: 140 °F @ 55 psig (60 °C @ 3.8 bar), liquid service
Maximum operating pressure: 90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

Bacterial Retention
>10^7 per cm² removal of Brevundimonas diminuta per ASTM F838

Sterilization
Autoclave: 121 to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 min, ≥ 3 cycles. Water wet membrane prior to autoclaving.
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in line steam sterilized.

Biological Safety
STyLUX® 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 STyLUX® 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 STyLUX® filters. Filters comply with European Commission Regulation No 10/2011.

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

**Sterile Filter Option**
- Standard capsule: CR
- Sterile capsule: GR

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

**Vent/Drain Ports**
- **Inline Configuration**
  - 0: No vent/drain valves
  - 2: Vent/drain valves at inlet and outlet
  - 4: Vent/drain valve at outlet
- **T-style Configuration**
  - 0: No vent; no drain
  - 1: No vent; standard drain plug
  - 2: Standard vent valve; standard drain plug
  - 3: Standard vent valve & drain plug; 3/4" sanitary flange gauge port
  - 4: Standard vent valve; no drain
  - 5: Standard vent valve; no drain; 3/4" sanitary flange gauge port
  - 6: No vent; no drain; 3/4" sanitary flange gauge port
  - A: No vent; sanitary drain valve
  - B: Standard vent valve; sanitary drain valve
  - C: Standard vent valve; sanitary drain valve; 3/4" sanitary flange gauge port

**Inlet/Outlet Connections**

<table>
<thead>
<tr>
<th>CR</th>
<th>2</th>
<th>SM</th>
<th>0.2 - 1</th>
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</table>

**Filter Grade**
- SM

**Retention Rating**
- 0.2 µm

**Effective Filtration Area**
- 7.3 ft² (0.68 m²) per 10" (25 cm)

**Product**
- STyLUX® hydrophilic PES membrane

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