The STyLUX® 0.4 µm hydrophilic PES capsule filter is manufactured using high quality components that are nontoxic, biologically inert and provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

**Materials of Construction**

All components of the STyLUX® filter capsule are either animal 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>
<th>CFR Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane</td>
<td>Polyethersulfone</td>
<td>21, 177.2440</td>
<td></td>
</tr>
<tr>
<td>Upstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>Downstream support</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>Outer guard</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>Core</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>End caps</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>Capsule shell</td>
<td>Polypropylene</td>
<td>21, 177.1520</td>
<td></td>
</tr>
<tr>
<td>Sealing method</td>
<td>Thermal bonding</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pore Size**

0.4 µm

**Minimum Bubble Point**

32 psi (2.2 bar), water

**Maximum Diffusion Rate**

25 mL/min per 10^7 @ 25 psi (1.72 bar), water

**Bacterial Retention**

>10^7 per cm² removal of *Serratia marcescens* per modified ASTM F838

**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, @ 35 psig (2.4 bar) gas
Maximum Operating pressure (liquid service): 90 psig @ 100 °F (6.2 bar @ 38 °C)
Maximum Operating pressure (gas service): 60 psig @ 100 °F (4.1 bar @ 38 °C)

**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 steamed in place (SIP).

**Biological Safety**

STyLUX® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and 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. No binders, adhesives or surfactants are used in the construction of STyLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011.

**Quality Assurance**

Each STyLUX® ST0.4 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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; non-sterile: CR
- Presterilized: GR

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

**Vent/Drain Ports**
- **Inline Configuration**
  - 0: No vents/drain
  - 2: Vent/drain at inlet and outlet
  - 4: Vent/drain at outlet

- **T-style Configuration**
  - 0: No vent; no drain
  - 2: No vent; standard 1/4" drain plug
  - 3: Std. vent & drain plug; 3/4" TC gage port
  - 4: Std. vent; no drain
  - 5: Std. vent; no drain; gage port
  - 6: No vent; no drain; gage port
  - A: No vent; sanitary drain valve
  - B: Std. vent; sanitary drain valve
  - C: Std. vent; san. drain valve; gage port

**Inlet / Outlet Connections**
- 00: 1" sanitary (TC) flange
- 02: 1" TC in & 3/8" hose barb out
- 08: 1" TC in & 3/4" hose barb out
- 09: 1" TC in & 9/16" hose barb out
- 0C: 1" TC in & 1/2" hose barb out
- 0D: 1" TC in & 1" hose barb out
- 22: 3/8" hose barb

**Body Style**
- N: Inline configuration
- T: T-style configuration

**Filter Length**

<table>
<thead>
<tr>
<th>Filter Grade</th>
<th>Retention Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Additional information about STyLUX® filter products is available in the Green Docs document which is viewable at https://www.meissner.com/downloads/stylux-gd001.pdf

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STyLUX is a registered trademark of Meissner Filtration Products.