**Description**
The STyLUX® SC0.1 filter is a hydrophilic PES membrane filter compatible with a wide range of liquids. It withstands a wide pH range (1-14) and can be used to remove contaminants from a broad range of pharmaceutical preparations, antibiotics, vaccines, protein solutions, virus suspensions, enzymes, buffers, ophthalmic solutions, reagents, salt solutions, nutrients, serum and blood-based products, and biologicals. The filter's asymmetrical structure provides bacteria and particle removal at high flow rates and low pressure drops. STyLUX® has very low binding characteristics for preservatives commonly used in the pharmaceutical industry and is compatible with most cleaning chemicals, sanitizers, and biocides.

The STyLUX® SC0.1 is a sterilizing grade filter designed specifically for the 100% removal of mycoplasma. It is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology, and related industries.

**Materials of Construction**
All components of the STyLUX® capsule filter are either animal component free (ACF) or in compliance with EMEA/410/01 Rev. 3 (EDQM 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>Filter membrane</td>
<td>Polyethersulfone (PES)</td>
<td>Title 21, 177.2440</td>
</tr>
<tr>
<td>Up/downstream support</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Core, outer guard, end caps</td>
<td>Polypropylene</td>
<td>Title 21, 177.1520</td>
</tr>
<tr>
<td>Capsule shell</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**
0.1 µm

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

**Minimum Bubble Point**
35 psi (2.41 bar) 70% IPA/30% water
36 psi (2.48 bar) in 60% IPA/40% water

**Bacterial Retention**
>10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838
>10⁷ per cm² removal of *Acholeplasma laidlawii* per modified 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 service
- Maximum temperature rating: 140 °F @ 35 psig (60 °C @ 2.4 bar), gas service
- Maximum operating pressure: 90 psig @ 100 °F (6.2 bar @ 38 °C), liquid service
- Maximum operating pressure: 60 psig @ 100 °F (4.1 bar @ 38 °C), gas service
- Maximum reverse pressure: 15 psig @ 100 °F (1.0 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. 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, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. 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® SC0.1 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.
### Sterile Filter Options
- Standard capsule: CR
- Sterile capsule: GR

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

### Vent/Drain Ports
- **Inline Configuration**
  - 0: No vents/drains
  - 2: Vent/drain at inlet and outlet
  - 4: Two sanitary valves with hose barbs
  - K: SPD vent/drain at inlet and outlet
  - L: SPD vent/drain at outlet
- **T-Style Configuration**
  - 0: No vent; no drain
  - 1: No vent; standard 1/4” drain plug
  - 2: Standard vent valve; standard, drain plug
  - 3: Standard vent & drain plug; 3/4” sanitary gage port
  - 4: Standard vent; no drain
  - 5: Standard vent; no drain; gage port
  - 6: No vent; no drain; gage port
  - A: No vent; sanitary drain valve
  - B: Standard vent; sanitary drain valve
  - C: Standard vent; sanitary drain valve; gage port

### Inlet/Outlet Connections
- 00: 1" sanitary flange
- 02: 1" sanitary flange in & 3/8" hose barb out
- 08: 1" sanitary flange in & 3/4" hose barb out
- 09: 1" sanitary flange in & 9/16" hose barb out
- 0C: 1" sanitary flange in & 1/2" hose barb out
- 0D: 1" sanitary flange in & 1" hose barb out
- 22: 3/8" hose barb
- 77: 3/4" sanitary flange
- 88: 3/4" hose barb
- 99: 9/16" hose barb
- CC: 1/2" hose barb
- DD: 1" hose barb

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

### Filter Length
- 1: 10"
- 2: 20"
- 3: 30"
- 4: 40"
- 5: 50"

### Product
- STyLUX® hydrophilic PES membrane

### Grade and Pore Size
- SC: 0.1 μm

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

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