**Description**

The EverLUX® STC0.1 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 capsule are either animal component free (ACF) 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:

- Filter membranes: Polyethersulfone (PES) CFR Title 21, 177.2440
- Up/downstream support: Polypropylene CFR Title 21, 177.1520
- Core, outer guard, end caps: Polypropylene CFR Title 21, 177.1520
- Capsule shell: Polypropylene CFR Title 21, 177.1520
- Sealing method: Thermal bonding

**Pore Size**

0.1 μm

**Maximum Diffusion Rate**

CS: 1.2 ft²: 5.3 mL/min @ 40 psi (2.76 bar), water
CL: 2.6 ft²: 11 mL/min @ 40 psi (2.76 bar), water

**Operating Characteristics**

- Operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)
- Maximum temperature rating: 160 °F @ 35 psig (72 °C @ 2.4 bar)
- Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service
- Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)
- Maximum operating pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas service

**Bacterial Retention**

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

**Sterilization**

- Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles. Water wet membrane first.
- 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 amebocyte 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 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 is clearly marked with filter type, lot number, and serial number.
Ordering Guide

Capsule Options
- Standard capsule: C
- Sterile capsule: G
- Opaque shell: O

Vent/Drain Ports
- 0: No vent/drain port
- 1: One luer port with cap, outlet side
- 2: Standard; two luer ports with caps
- 4: Two sanitary valves with hose barbs
- 5: One sanitary valve with hose barb, outlet side
- 6: One sanitary valve with hose barb, inlet side

Effective Filtration Area
- 2.6 ft² (0.24 m²): L
- 1.2 ft² (0.11 m²): S

Inlet/Outlet Connections
- 00: 1" sanitary flange
- 02: 1" sanitary flange in; 3/8" hose barb out
- 09: 1" sanitary flange in; ½" hose barb out (flexible tubing)
- 77*: ¾" sanitary flange
- LL: 1" sanitary flange, long neck
- 22: 3/8" hose barb

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

Product Grade Pore Size
- EverLUX® hydrophilic PES membrane: STC 0.1 μm

*3/4 sanitary flange fitting option is only available for CS2 and CL2.
Additional information about this filter product is available in the EverLUX® Green Docs document at www.meissner.com/green-docs.

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