SteriLUX®

0.4 µm VTH-grade Large Capsule Filter (UltraCap® H.D. Model)

**Description**
SteriLUX® VTH0.4 is a hydrophilic PVDF membrane filter with low protein binding properties and broad chemical compatibility. It is recommended for sterile 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.

The SteriLUX® VTH0.4 filter 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 SteriLUX® 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:

- **Membrane:** Polyvinylidene fluoride (PVDF) CFR Title 21, 177.2510
- **Upstream support:** Polypropylene CFR Title 21, 177.1520
- **Downstream support:** Polypropylene CFR Title 21, 177.1520
- **Outer guard:** Polypropylene CFR Title 21, 177.1520
- **Core:** Polypropylene CFR Title 21, 177.1520
- **End caps:** Polypropylene CFR Title 21, 177.1520
- **Capsule shell:** Polypropylene CFR Title 21, 177.1520
- **Sealing method:** Thermal bonding

**Pore Size**
0.4 µm

**Effective Filtration Area**
7.9 ft² (0.73 m²) per 10"

**Minimum Bubble Point**
28 psi (1.93 bar), water

**Maximum Diffusion Rate**
15 mL/min per 10" (25 cm) @ 22 psi (1.52 bar), water

**Bacterial Retention**
>10⁷ cfu 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: 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.
- Irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules. Capsules must not be in-line steam sterilized.

**Biological Safety**
SteriLUX® 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 SteriLUX® 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 SteriLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011.

**Quality Assurance**
Each SteriLUX® VTH0.4 is supplied with a Certificate of Quality verifying the high standards and superior performance of the product. SteriLUX® 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 SteriLUX® 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: Vent/drain valve at outlet
- 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 valve & drain plug; 3/4” sanitary gage port
- 4: Standard vent valve; no drain
- 5: Standard vent valve; no drain; gage port
- 6: No vent; no drain; gage port
- A: No vent; sanitary drain valve
- B: Standard vent; drain valve
- C: Standard vent/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
- **SteriLUX® hydrophilic PVDF membrane**
- **VTH**: 0.4 μm

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

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