

SteriLUX®

0.1 µm VTH-grade Mini Capsule (CM2/CK2 Model)

Description

The SteriLUX® VTH0.1 filter capsule is a sterilizing grade hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for sterilizing filtration and mycoplasma removal 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, alcohols, and sanitizing agents.

The VTH0.1 filter capsule 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® mini capsule are animal component free (ACF). 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 housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Pore Size 0.1 µm

Minimum Bubble Point 70 psi (4.8 bar), water
26 psi (1.8 bar), 60% IPA/40% water
25 psi (1.7 bar), 70% IPA/30% water

Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838

Operating Characteristics

Operating temperature range: 32 °F to 122 °F (0 °C to 50 °C)
Maximum temperature rating 160 °F @ 35 psig (72 °C @ 2.4 bar)
Maximum operating pressure: 100 psig @ 122 °F (6.9 bar @ 50 °C)
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.

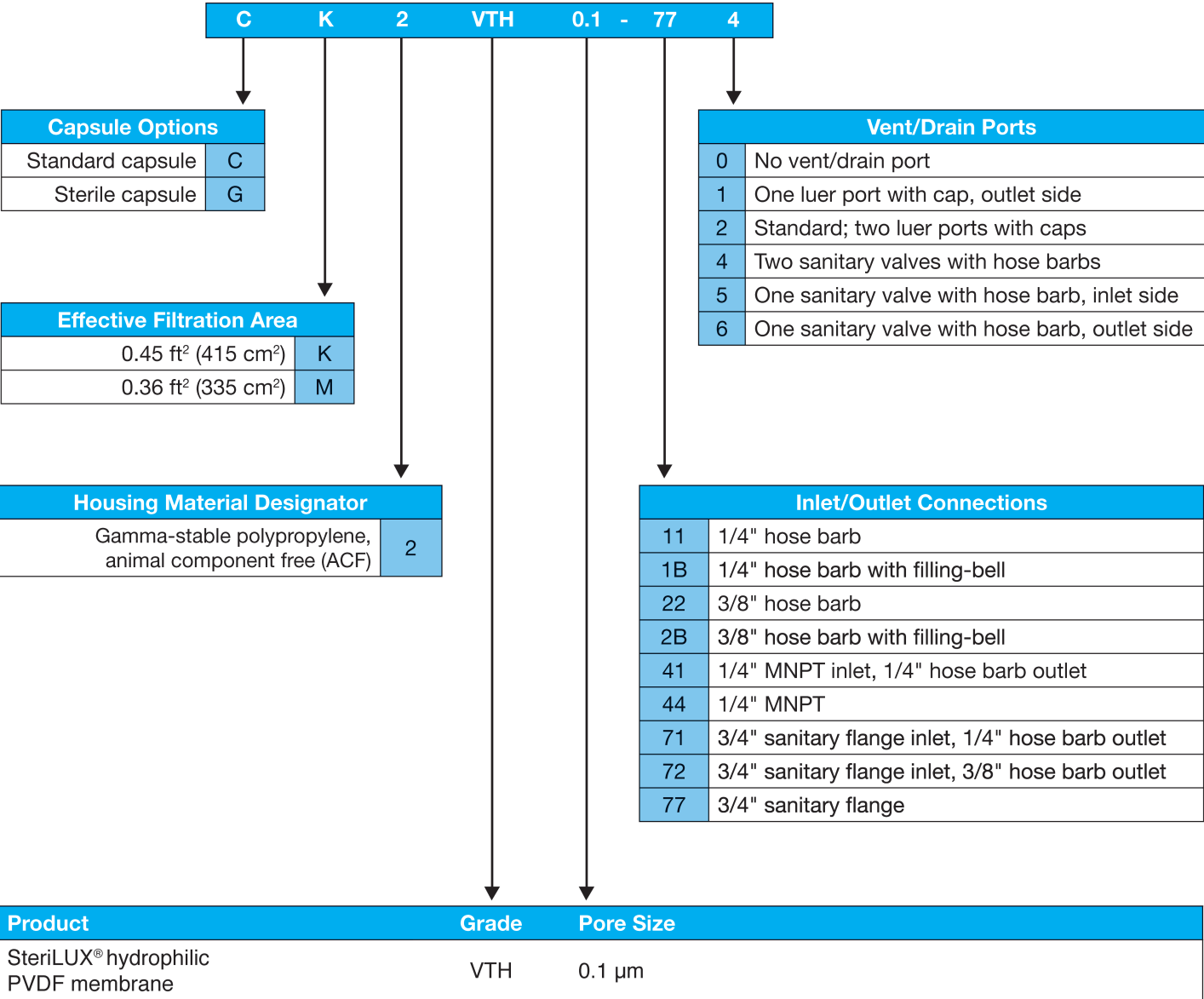
Biological Safety

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* amoebocyte 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

SteriLUX® VTH0.1 filters are 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.

Ordering Guide



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

SteriLUX® is a registered trademark of Meissner Filtration Products, Inc.
© 2023, 2016 Meissner Filtration Products, Inc. All rights reserved.