SteriLUX®

0.2 µm VTH-grade 50 mm Filter (CB2 Model)

Description

SteriLUX® 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, UPW, chemicals, alcohols, and sanitizing agents.

The SteriLUX® VTH0.2 capsule 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 encapsulated discs are animal component free. These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Media	Polyvinylidene fluoride	CFR Title 21, 177.2510
Downstream support	Polypropylene	CFR Title 21, 177.1520
Capsule housing	Polypropylene	CFR Title 21, 177.1520
Sealing method	Thermal Bonding	

Pore Size	0.2 µm
EFA	19.6 cm^2
Bacterial Retention	>10^7 cfu/cm^2 retention of *Brevundimonas diminuta* per ASTM F838
Minimum Bubble Point	50 psi (3.44 bar), water 18 psi (1.24 bar), 60% IPA/40% water 17 psi (1.17 bar), 70% IPA/30% water

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	160 °F @ 35 psig (71 °C @ 2.4 bar)
Maximum operating pressure:	80 psig @ 100 ºF (5.5 bar @ 38 ºC)
Maximum reverse pressure:	15 psig @ 100 ºF (1.0 bar @ 38 ºC)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.
Capsules must not be in-line steam sterilized.

Biological Safety

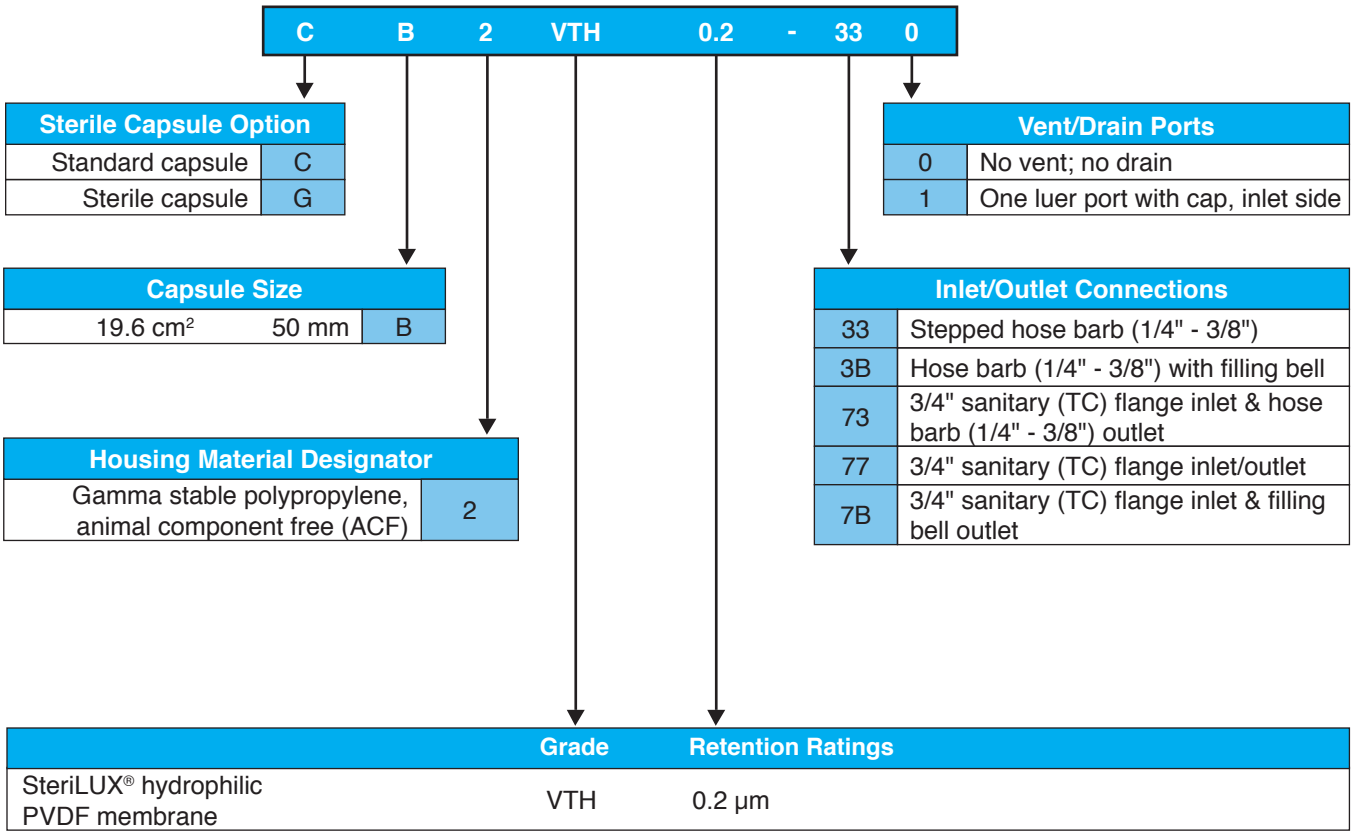
SteriLUX® filters meet the requirements as specified in the current USP <88> Class VI plastics, physicochemical, oxidizable substances, and USP <87> cytotoxicity tests. Bacterial endotoxin levels in aqueous extracts of SteriLUX® filters are less than 0.5 EU/mL, as determined using the *Limulus* amebocyte lysate (LAL) USP <85> test. No adhesives, binders, or surfactants are used in the construction of SteriLUX® filters. Filters comply with European Commission Regulation No 10/2011. The 50 mm capsules are TSE/BSE/animal component free (ACF).

Quality Assurance

SteriLUX® VTH0.2 filters are supplied with a Certificate of Quality verifying the high standards and superior performance of the product. 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 filter is integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

MEISSNER FILTRATION PRODUCTS

Ordering Guide



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

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