

SteriLUX®

VTH0.1 Capsule

Description

Identical to the VMH0.1, the sterilizing grade SteriLUX® VTH0.1 PVDF hydrophilic filter capsule provides the added benefit of certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

Materials of Construction

All components of the SteriLUX® filter capsule are either animal free 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:

Membrane:	Polyvinylidene fluoride	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

Maximum Diffusion Rate
1.6 ft² (0,15 m²): ≤ 4 mL/min @ 56 psi (3,86 bar), water
3.3 ft² (0,31 m²): ≤ 8.5 mL/min @ 56 psi (3,86 bar), water

Bacterial Retention
>10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838
Typically 10⁵ per cm² removal of *Acholeplasma laidlawii* per modified ASTM F838

Operating Characteristics

Normal operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)
Maximum operating temperature rating: 160 °F @ 35 psig (72 °C @ 2,4 bar)
Maximum operating pressure (liquid service): 75 psig @ 100 °F (5,2 bar @ 38 °C)
Maximum operating pressure (gas service): 50 psig @ 100 °F (3,4 bar @ 38 °C)

Sterilization

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

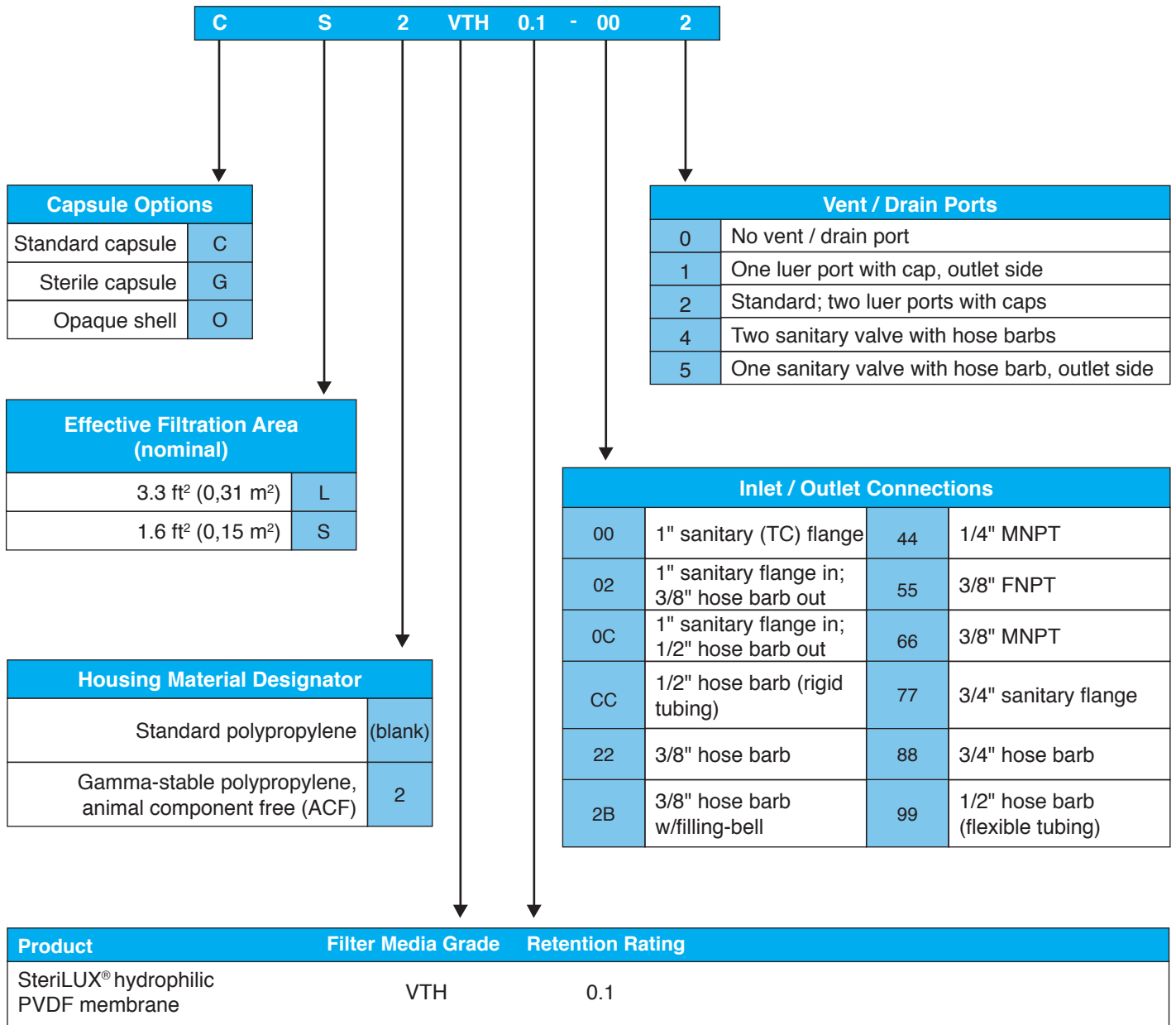
Biological Safety

SteriLUX® filters meet the requirements as specified in the current USP Class VI plastics, physicochemical, oxidizable substances, and cytotoxicity tests. 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

Each SteriLUX® VTH0.1 filter 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.

Ordering Guide



Additional information about SteriLUX[®] filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/sterilux-gd003.pdf>

SteriLUX is a registered trademark of Meissner Filtration Products.