

SteriLUX®

VTH0.1 UltraCap® H.D.

Description

The SteriLUX® VTH grade 0.1 µm hydrophilic PVDF capsule filter is manufactured using high quality components that are nontoxic and biologically inert and 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 shell:	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 20 mL/min per 10" (25 cm) @ 56 psi (3,86 bar), water

Bacterial Retention >10⁷ per cm² removal of *Brevundimonas diminuta* per ASTM F838-05

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 (liquid service): 90 psig @ 100 °F (6,2 bar @ 38 °C)

Maximum Operating pressure (gas service): 60 psig @ 100 °F (4,1 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 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

CR 2 VTH 0.1 - 1 T 00 4

Sterile Filter Option	
Standard; non-sterile	CR
Presterilized	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 at outlet
T-style Configuration	
0	No vent; no drain
1	No vent; standard 1/4" drain plug
2	Std. vent valve; std. drain plug
3	Std. vent & drain plug; 3/4" TC gage port
4	Std.vent; no drain
5	Std. vent; no drain; gage port
6	No vent; no drain; gage port
A	No vent; sanitary drain valve
B	Std. vent; sanitary drain valve
C	Std. vent; san. drain valve; gage port

Inlet / Outlet Connections			
00	1" sanitary (TC) flange	77	3/4" sanitary flange
02	1" TC in & 3/8" hose barb out	88	3/4" hose barb
08	1" TC in & 3/4" hose barb out	99	9/16" hose barb
09	1" TC in & 9/16" hose barb out	AA	1/2" male Flaretek®
0C	1" TC in & 1/2" hose barb out	BB	3/4" male Flaretek®
0D	1" TC in & 1" hose barb out	CC	1/2" hose barb
22	3/8" 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	Filter Grade	Retention Rating
SteriLUX® PVDF membrane (hydrophilic)	VTH	0.1

Additional information about SteriLUX® filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/sterilux-gd003-2.1.pdf>

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