

# STyLUX®

## SM0.4 Capsule

### Description

The STyLUX® SM grade 0.4 µm PES hydrophilic filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

### Materials of Construction

All components of the STyLUX® 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:	Polyethersulfone	CFR Title 21, 177.2440
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** 0.4 µm

**Minimum Bubble Point** 32 psi (2,2 bar), water

**Bacterial Retention** >10<sup>7</sup> per cm<sup>2</sup> removal of *Serratia marcescens* per modified ASTM F838-05

### Operating Characteristics

Operating temperature range: 32 °F to 100 °F (0 °C to 38 °C)

Maximum 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. Water wet membrane prior to autoclaving.

Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.

Capsules must not be steamed in place (SIP).

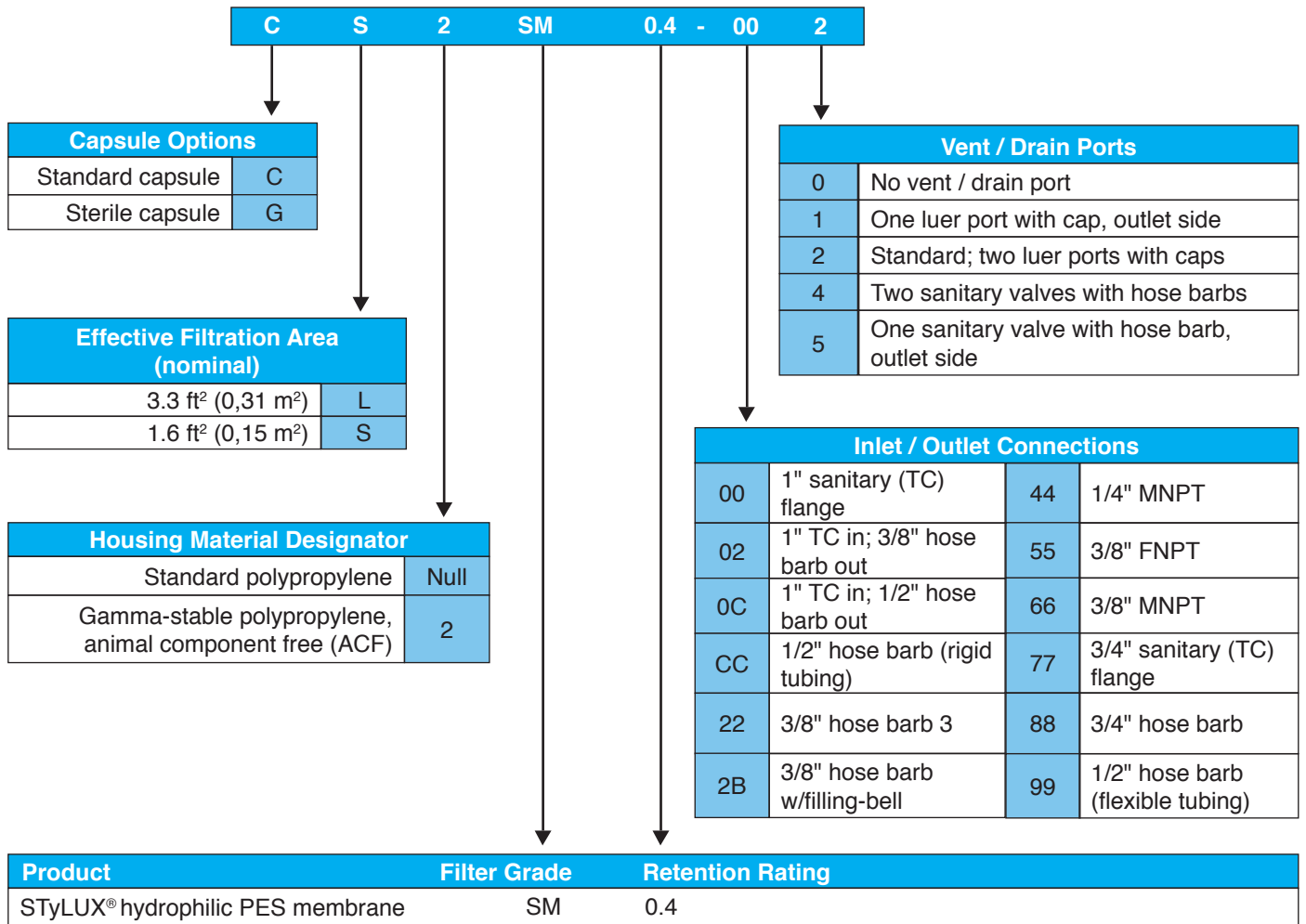
### Biological Safety

STyLUX® 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 STyLUX® 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 STyLUX® filters. Filters comply with Commission Regulation (EU) No 10/2011.

### Quality Assurance

STyLUX® 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 STyLUX® filter is integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

## Ordering Guide



Additional information about STyLUX® filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/stylux-gd001-2.1.pdf>

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