

# SteriLUX®

## 0.4 µm VMH-grade Mini Capsule Filter (CM2/CK2 Model)

### Description

The SteriLUX® VMH grade 0.4 µm PVDF hydrophilic filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

### Materials of Construction

All components of the SteriLUX® mini capsule are animal free. 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** 0.4 µm

**Minimum Bubble Point** 28 psi (1.9 bar), water

**NVR Extractables** ≤ 0.05% in water

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

### Operating Characteristics

Operating temperature range: 32 °F to 122 °F (0 °C to 50 °C)

Maximum operating pressure: 100 psig (6,9 bar)

### 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).

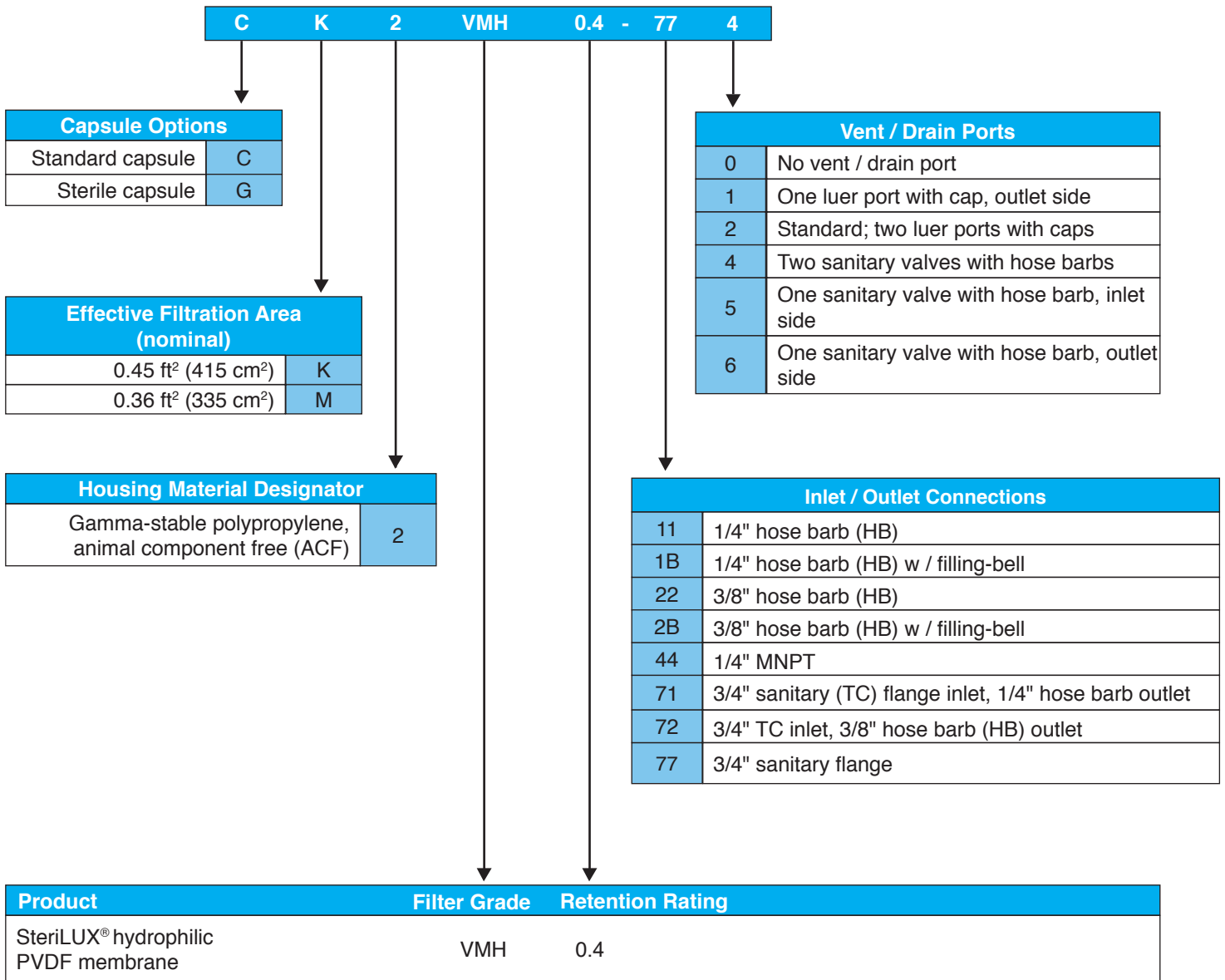
### Biological Safety

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

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<sup>®</sup> filter products is available in the Green Docs document at [www.meissner.com/green-docs](http://www.meissner.com/green-docs).

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