# **Steridyne®**

## 0.2 µm VMF-grade 50 mm Filter (CB2 Model)

### Description

The Steridyne® VMF0.2 is a hydrophobic PVDF membrane filter optimized for critical air and gas applications. Designed for bidirectional flow, this filter is well suited for applications requiring complete removal of bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air, and sterile venting of carboys, filling vessels, bioreactors and small product or intermediate tanks. Steridyne® capsule filters are manufactured using gamma irradiation tolerant materials and are ideal for integration into single-use systems needing aeration or gas exhaust.

#### **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:

Membrane:Polyvinylidene fluoride (PVDF)CFR Title 21, 177.2510Downstream Support:PolypropyleneCFR Tilte 21, 177.1520Capsule Housing:PolypropyleneCFR Tilte 21, 177.1520

Sealing Method: Thermal Bonding

Pore Size 0.2 μm (liquid-rated, sterilizing grade)

Effective Filtration Area 19.6 cm<sup>2</sup>

Minimum Bubble Point 18 psi (1.24 bar) in 60% IPA/40% water, with air or nitrogen

17 psi (1.17 bar) in 70% IPA/30% water, with air or nitrogen

Typical Air Flow Rate 4.0 L/min @ 1 psid (0.17 Nm³/hr at Δp 50 mbar)

Bacterial Retention >10<sup>7</sup> cfu/cm<sup>2</sup> retention of Brevundimonas diminuta per ASTM F838

**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 °F (5.5 bar @ 38 °C)

Maximum reverse pressure: 15 psig @ 100 °F (1.0 bar @ 38 °C)

#### Sterilization

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

#### **Biological Safety**

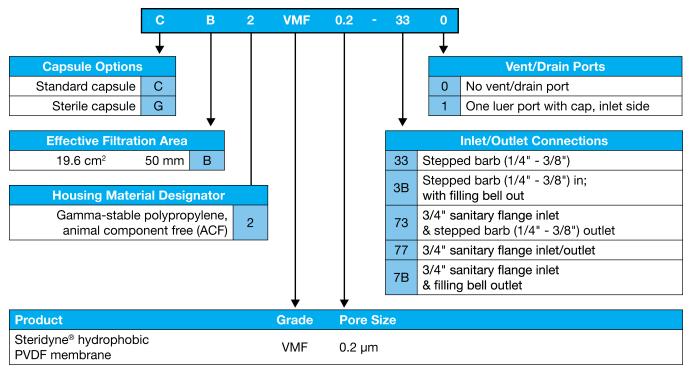
Steridyne® filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity, physicochemical, and USP 43 oxidizable substances tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No. 10/2011. Capsules are TSE/BSE/animal component free (ACF).

#### **Quality Assurance**

Steridyne® 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.



#### **Ordering Guide**



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

