# Ultradyne®

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

***Description***

The Ultradyne® TA0.2 vent filter is a sterilizing grade hydrophobic PTFE membrane filter optimized for applications requiring complete removal of contaminant 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. The product also has broad chemical compatibility and is suitable for removal of particles and microorganisms from aggressive liquids, including strong acids and bases, and organic solvents.

***Materials of Construction***

All components of the Ultradyne® 50 mm filter are animal component free (ACF). These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

| | | |
|---|---|---|
| Membrane | Polytetrafluoroethylene (PTFE) | CFR Title 21, 177.1550 |
| Downstream support | Polypropylene | CFR Title 21, 177.1520 |
| Capsule housing | Polypropylene | CFR Title 21, 177.1520 |
| Sealing method | Thermal Bonding | |

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|---|---|
| ***Pore Size*** | 0.2 µm |
| ***Effective Filtration Area*** | 19.6 $cm^2$ |
| ***Bacterial Retention*** | >$10^7$ cfu/$cm^2$ retention of *Brevundimonas diminuta* per ASTM F838 |
| ***Typical Air Flow Rate*** | >8.5 standard L/min at 0.2 bar, differential<br>>0.3 standard CFM at 3.0 psi, differential |
| ***Minimum Bubble Point*** | 16 psi (1.10 bar), 60% IPA/40% water, air<br>16 psi (1.10 bar), 70% IPA/30% water, nitrogen |

***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 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.
Capsules must not be in-line steam sterilized. Irradiation is not recommended.

***Biological Safety***

Ultradyne® filters meet the requirements as specified in the current USP <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No 10/2011. The 50 mm capsules are TSE/BSE/animal component free (ACF).

***Quality Assurance***

Ultradyne® 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 Ultradyne® filter is clearly marked with filter type, lot number, and serial number.

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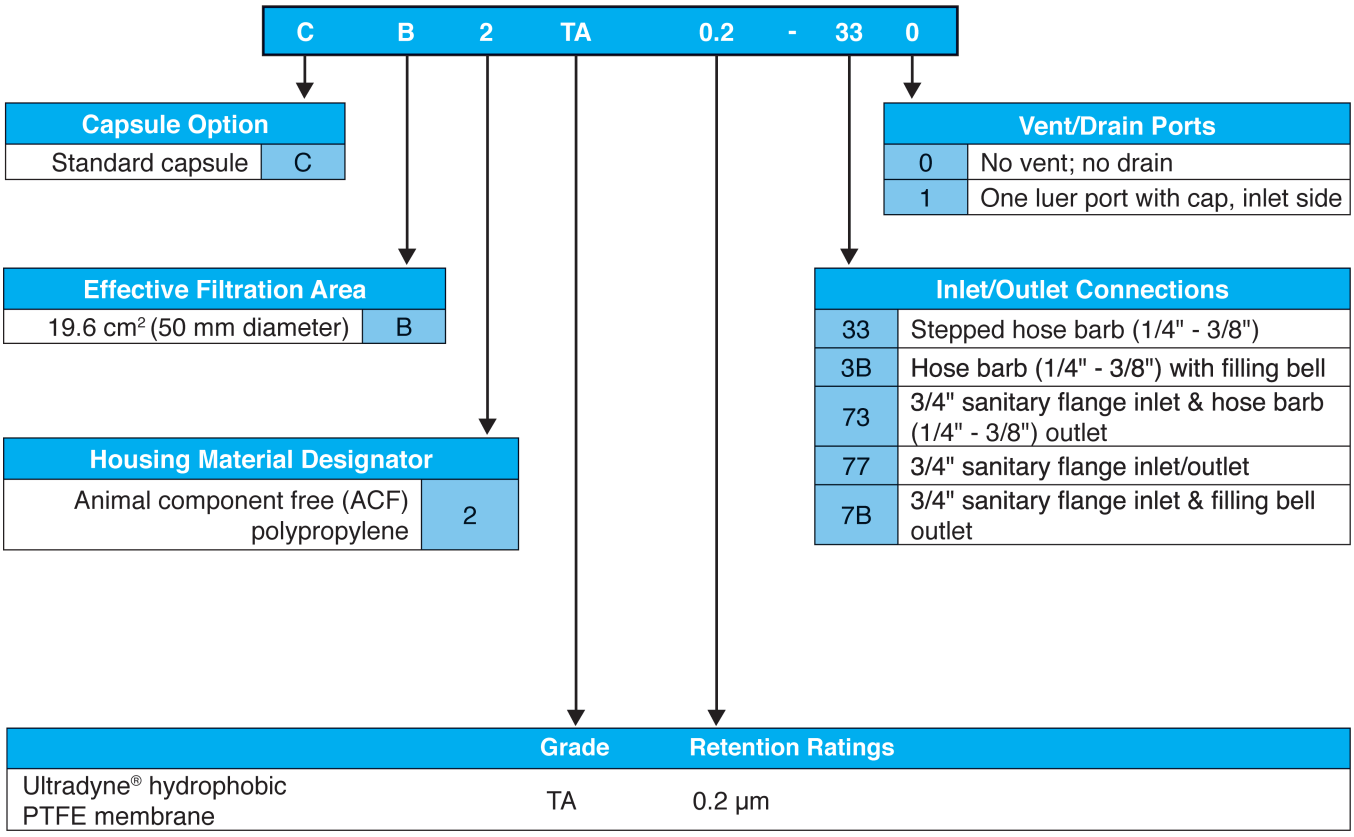
## *Ordering Guide*




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

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