# **Ultradyne**

# 0.1 µm TM-grade Standard Capsule Filter — CS(2), CL(2), CJ2 Model

### Description

The Ultradyne® TM0.1 filter cartridge is a hydrophobic PTFE membrane filter offering maximum chemical compatibility with minimal extractables in a wide range of fluids and applications. This filter provides reliable removal of particles and microorganisms from aggressive liquids, including strong acids and bases, and organic solvents. Ultradyne® is 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 tanks, lyophilizers, and autoclaves. The Ultradyne® filter provides sterility assurance, high flow rates and throughput under demanding conditions.

#### Materials of Construction

All components of the filter are either animal free or in compliance with EMA/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:	Polytetrafluoroethylene (PTFE)	CFR Title 21, 177.1550
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 0.1 μm

Minimum Bubble Point 20 psi (1.38 bar) in 60% IPA/40% water, with air or nitrogen 19 psi (1.31 bar) in 70% IPA/30% water, with air or nitrogen

Maximum Diffusion Rate CS: 3.0 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air

CL: 6.5 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air CJ: 13 mL/min @ 15 psi (1.03 bar), 60% IPA/40% water, with air

 Typical Air Flow Rate
 CS: 4.81 scfm @ 1 psid (5.93 Nm³/hr @ Δp 50 mbar)

CL: 6.45 scfm @ 1 psid (7.95 Nm<sup>3</sup>/hr @ \Delta p 50 mbar)

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

Operating Characteristics

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

Maximum operating temperature: 160 °F @ 35 psig (71 °C @ 2.4 bar)

Maximum operating pressure: 75 psig @ 100 °F (5.2 bar @ 38 °C), liquid service Maximum operating pressure: 50 psig @ 100 °F (3.4 bar @ 38 °C), gas service

Maximum reverse pressure: 15 psig @ 100 °F (1.1 bar @ 38 °C)

#### Sterilization

Autoclave: 121 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**

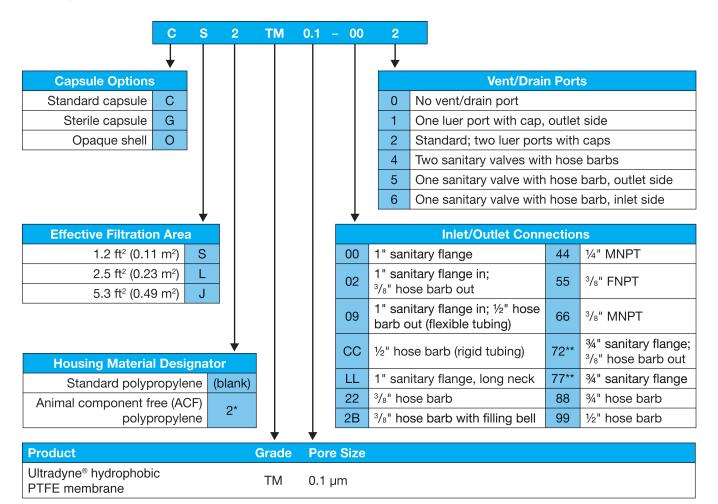
Ultradyne® filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity and pyrogenicity tests. No binders, adhesives, or surfactants are used in its construction. Filters comply with Commission Regulation (EU) No. 10/2011.

#### **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 unique serial number.



#### Ordering Guide



<sup>\*</sup>CJ2 filters are only available with an animal component free (ACF) polypropylene housing.

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



<sup>\*\*3/4</sup> sanitary flange fitting option is only available for CS2, CL2, and CJ2 capsules.