

# Ultradyne®

## TM0.2 Mini Capsule

### **Description**

The Ultradyne® TM grade 0.2 µm hydrophobic PTFE filter capsule is manufactured using high quality components that are nontoxic and biologically inert.

### **Materials of Construction**

All components of the Ultradyne® 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:	Polytetrafluoroethylene	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** 0.2 µm

**Minimum Bubble Point** 14 psi (1,0 bar), 60% IPA / 40% water

### **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.

Capsules must not be steamed in place (SIP).

Gamma irradiation is not recommended.

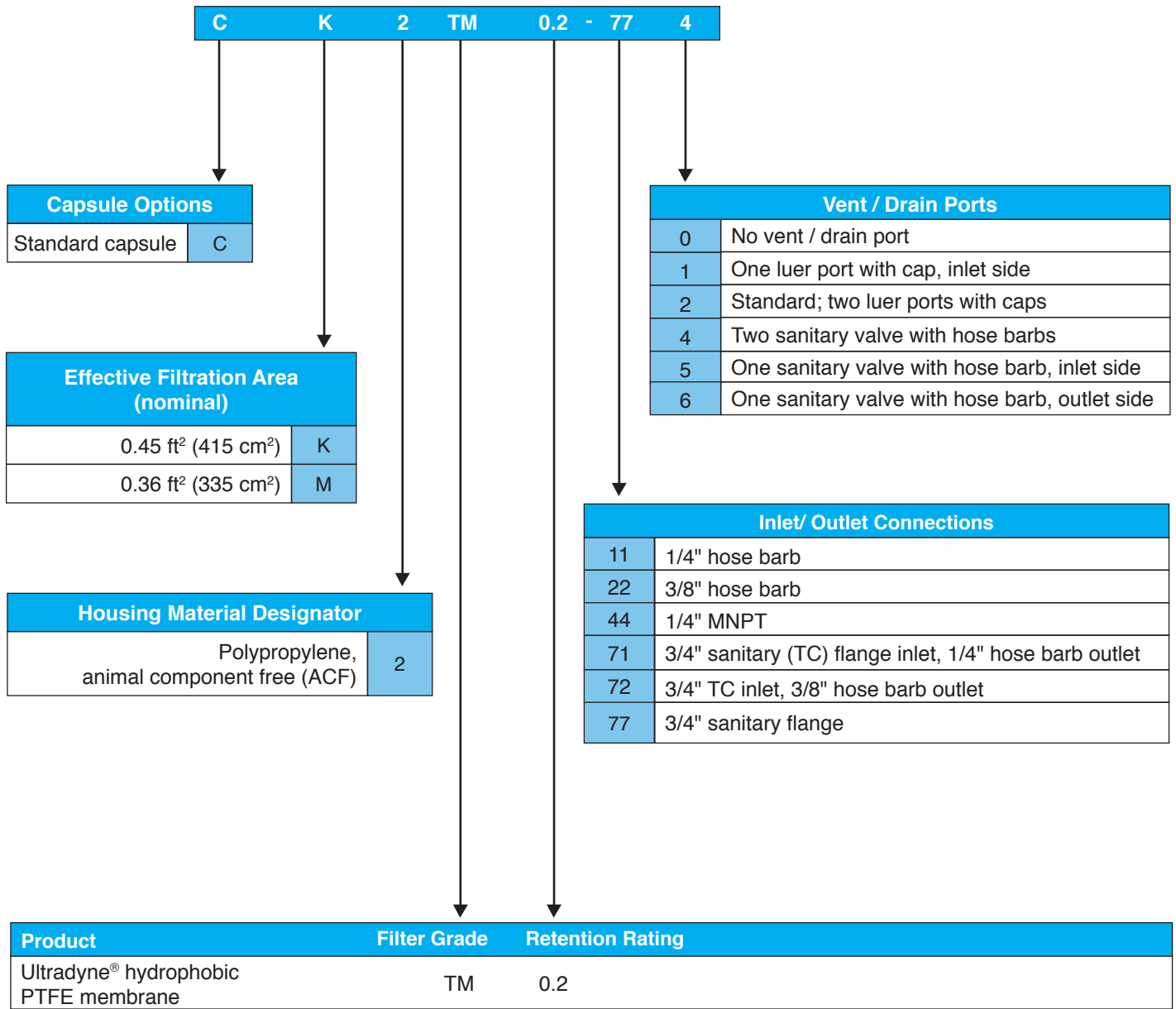
### **Biological Safety**

Ultradyne® filters meet the requirements as specified in the current USP Class VI plastics, cytotoxicity, and pyrogenicity tests. No binders, adhesives or surfactants are used in the construction of Ultradyne® filters. 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 integrity tested during manufacture and is clearly marked with filter type, lot number and serial number.

## Ordering Guide



Additional information about Ultradyne<sup>®</sup> filter products is available in the Green Docs document which is viewable at <https://www.meissner.com/downloads/ultradyne-gd006-2.1.pdf>