



## STERILE SYRINGE FILTER

These filters are designed for applications where sterility of the affluent is mandatory (Sterile Compounding and Pharmaceutical use). The product contains a pharmaceutical grade PES membrane (sterilizing Grade) and the filters are built in a 10,000-class clean room, flushed, dried and 100% integrity tested prior to packaging. The product is factory sterilized by Ethylene Oxide gas (ETO) ensuring sterility.

## Technical Data Sheet

**Catalog Number: D25CS020FLM-PH-ETO**



### **Materials of Construction**

**Filter Membrane:** 0.2 um, Pharmaceutical Grade Polyethersulfone (PES) sterilizing grade- Hydrophilic

**Supports:** Polypropylene

**Capsule Body:** Polypropylene

### **Filter Dimensions and Specifications**

**Outer Diameter:** 33 mm (1.30")

**Capsule Body Thickness:** 5.1 mm (0.200")

**Length, Fitting to Fitting:** 24 mm (0.945")

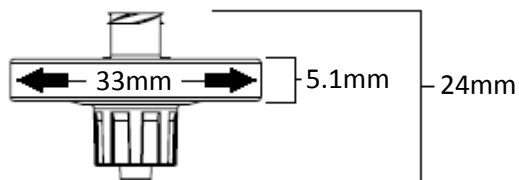
**Filter Area:** 4.6 cm<sup>2</sup> (0.7 in<sup>2</sup>); competitive standard contains 3.5 cm<sup>2</sup>

**Sterilization:** The filter is factory sterilized with Ethylene Oxide Gas (ETO)

**Inlet Fitting:** Luer Loc Female

**Outlet Fitting:** Luer Loc Male

**Volume Filtered:** 60 ml to 200 ml



### ***Integrity Data***

<b>Pore Size</b>	<b>Min, Bubble Point, 25°C</b>	<b>Challenge Microorganisms</b>	<b>CFU per cm<sup>2</sup></b>
0.20 µm	≥3.5 bar (50 psi)	Brevundimonas Diminuta (ATCC 19146)	7

### ***Operating Parameters***

Maximum Working Pressure: 5.5 bar (80 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (forward): 4.1 bar (60 Psi) @ 25 °C (77 °F)

Maximum differential Pressure (reverse): 2.1 bar (30 Psi) @ 25 °C (77 °F)

Maximum Operating Temperature: 80 °C (176 °F)

Recommended Replacement Pressure: 2.4 bar (35.3 Psi)

### ***Safety***

UPS Bacteria Endotoxins: ≤25 EU/ml

Factory Sterilized: Ethylene Oxide Gas (ETO)

Product was 100% Integrity Tested and flushed with filtered water @ 0.05 µm

### ***Regulatory***

Complies with the guideline in USP 797

ASTM F838-05 - Bacterial Retention

FDA 21 CFR 177.1655

USP Class VI - Biological Reactivity

ISO 10993-Part 1.5 - Cytotoxicity

ISO 14001; ISO 13485; OHSMS 18001 Certified.

ASTM Hemolysis testing