

The Hydrophobic PTFE Membrane Cartridge Filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiSure TF Hydrophobic PTFE Membrane Cartridge Filters**

Catalog No. : CPTF5001F0SS101  
 Type : CPTF  
 Pore Size : 0.2 µm  
 Lot Number : CT5984L      Sl.No. 085  
 Manufacturing Date : 2024 - 12  
 Expiry Date : 2029 - 12

### SPECIFICATION

<b>Length</b>	2.5"
<b>Filter Media</b>	Hydrophobic PTFE Membrane
<b>Drainage Layers</b>	Polypropylene
<b>Plastic Components</b>	Polypropylene
<b>Differential Pressure</b>	< 3.5 Kg/cm <sup>2</sup> at 25°C
<b>Maximum operating Temperature</b>	80 °C at < 2 Kg/cm <sup>2</sup>
<b>Reverse Pressure</b>	< 0.7 Kg/cm <sup>2</sup> at 25°C
<b>Sterilization</b>	100 Autoclave/ Steam sterilization cycles at 121°C for 30 minutes each

### LOT RELEASE CRITERIA

- 100% Integrity Tested** : The cartridge filters have been tested for integrity by Bubble point Test using 70% IPA/Water solution. Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 3.0 ml /10 min at 2.0 kg/cm<sup>2</sup>
- Typical Air Flow Rate** : 8.0 Nm<sup>3</sup>/Hr at 0.07 kg/cm<sup>2</sup>
- Microbial Challenge Test** : Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

### VALIDATED FOR

- Heat Stability** : Maintains integrity after 100 autoclave/ Steam sterilization cycles at 121°C for 30 minutes each.
- Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
- Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
- Cytotoxicity** : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.
- Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)1(i).
- Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).

### CUSTOMER SUPPORT

**mdi** offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.

T. No.: COQ/CAR/008-00



Head of Quality Assurance

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**An ISO 9001 Company**