

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. : CPTF5001E0SS101  
 Type : CPTF  
 Pore Size : 0.2 µm  
 Lot Number : CT8497G      SI.No. 004

### 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:  $\geq 22$  psi (1.52 Bars)
- Water Intrusion Rate** :  $\leq 3.0$  ml /10 min at 2.0 kg/cm<sup>2</sup>
- Air Flow Rate** :  $\geq 8.0$  Nm<sup>3</sup>/Hr at 0.07 kg/cm<sup>2</sup>
- Microbial Challenge Test** : Retains  $\geq 10^7$  organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.
- VALIDATED FOR**
- Heat Stability** : Maintains integrity after 100 autoclave/ Steam sterilization cycles at 121°C for 30 minutes each.
- Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
- 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.



Head of Quality Assurance

Issue Date: 24-Jul-17

**Advanced Microdevices Pvt. Ltd.**  
 21, Industrial Area, Ambala Cantt, INDIA,  
 Tel: +91-171-2699290/ 2699274  
 Website: www.mdimembrane.com  
 Email: info@mdimembrane.com

**An ISO 9001 Company**