

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. : CPTF5601A0SS101
 Type : CPTF
 Pore Size : 0.2 µm
 Lot Number : CT98711 SI.No. 014
 Manufacturing Date : 2021 - 09
 Expiry Date : 2026 - 09

SPECIFICATION

| | |
|--------------------------------------|--|
| Length | 30" |
| Filter Media | Hydrophobic PTFE Membrane |
| Drainage Layers | Polypropylene |
| Plastic Components | Polypropylene |
| Differential Pressure | < 3.5 Kg/cm ² at 25°C |
| Maximum operating Temperature | 80 °C at < 2 Kg/cm ² |
| Reverse Pressure | < 0.7 Kg/cm ² at 25°C |
| Sterilization | 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 Air Diffusion flow test and Bubble point test using 70% IPA/Water solution.
 Diffusion flow was: ≤ 130 ml/min at 1.12 Kg/cm²
 Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 39 ml/10 min at 2.0 kg/cm²
- Typical Air Flow Rate** : 600 Nm³/Hr @ 0.10 Kg/cm²
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² 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.
- 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.



Head of Quality Assurance

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An ISO 9001 Company