

# Certificate of Quality

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

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

Catalog No. : CPTH5601A0SS101  
 Type : CPTH  
 Pore Size : 0.2 µm  
 Lot Number : CT9301I      SI.No. 015  
 Manufacturing Date : 2021 - 09  
 Expiry Date : 2026 - 09

### SPECIFICATION

<b>Length</b>	30"
<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>	95 °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>	By Autoclaving or Steam-in-place (SIP)

### 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/cm<sup>2</sup>  
 Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 39 ml/10 min at 2.0 kg/cm<sup>2</sup>
- Typical Air Flow Rate** : 600 Nm<sup>3</sup>/Hr @ 0.10 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 F838-05 methodology.

### VALIDATED FOR

- Heat Stability** : Maintains integrity after 80 Steam sterilization cycles at 135 °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**