

Certificate of Quality

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

AseptiVent TF Hydrophobic PTFE Membrane Capsule Filters

Catalog No. : LTLX5401EEXX101
 Type : LTL
 Pore Size : 0.2 µm
 Lot Number : LT8267G SI.No. 002

SPECIFICATION

Length	10"
Filter Media	Hydrophobic PTFE Membrane
Drainage Layers	Polypropylene
Differential Pressure	< 4Kg/cm ² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm ²
Sterilization	30 autoclaving cycles at 125 °C of 30 minutes each

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The capsule filters have been tested for integrity by Air Diffusion flow test and Bubble point test using 70% IPA/Water solution.
 Diffusion flows were: ≤ 45 ml/min at 1.12 Kg/cm²
 Bubble point was: ≥ 22 psi (1.52 Bar)
- Water Intrusion Rate** : ≤ 13 ml /10 min at 2.0 kg/cm²
- Air Flow Rate** : ≥ 200 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 30 autoclaving cycles at 125 °C of 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

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An ISO 9001 Company