

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

AseptiVent VF-γ Hydrophobic PVDF Membrane Capsule Filters

Catalog No. : DVLX5301AURX101
 Type : DVL
 Pore Size : 0.2 μm
 Lot Number : DV5504L SI.No. 084
 Manufacturing Date : 2024 - 12
 Expiry Date : 2029 - 12

SPECIFICATION

Length	5"
Filter Media	Hydrophobic PVDF Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm ² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm ²
Sterilization	Can be sterilized by Gamma Irradiation upto 50 kGy

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The capsule filters have been tested for integrity by Bubble point Test using 50% IPA/Water solution. Bubble point was: ≥ 18 psi (1.24 Bar)
- Typical Air Flow Rate** : 2.5 Nm³/Hr at 0.07 kg/cm²
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

VALIDATED FOR

- Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
- Extractable** : Within limits as specified in USP.
- 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.

T. No.: COQ/CAP/017-01



Head of Quality Assurance

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An ISO 9001 Company