mdi
Membrane Technologies

Certificate of Quality

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.	: LVLX5401EERT101	
Type	: LVL	
Pore Size	: 0.2 µm	
Lot Number	: LV8804L	Sl.No. 075
Manufacturing Date	: 2024 - 12	
Expiry Date	: 2029 - 12	

SPECIFICATION

Length	10”
Filter Media	Hydrophobic PVDF Membrane
Drainage Layers	Polyester
Differential Pressure	< 4Kg/cm² at 30 °C
Housing	Polypropylene
Maximum Operating Temperature	80 °C @ < 2 Kg/cm²
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 : 35 Nm³/Hr at 0.14 kg/cm²

Microbial Challenge Test : Retains ≥ 10^7 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