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.	: DVLX5101AAXX301	
Type	: DVL-S	
Pore Size	: 0.2 µm	
Lot Number	: DV7567G	Sl.No. 005
Ster. No.	: R012	
Expiry Date	: 2019 - 07	

SPECIFICATION

Length	1"
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	Pre sterilized by Gamma Irradiation

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)

Air Flow Rate : ≥ 2.0 Nm³/Hr at 0.14 kg/cm²

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.

Sterility : Samples passed the sterility test in accordance with U.S. pharmacopoeia.

VALIDATED FOR

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.

Head of Quality Assurance

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An ISO 9001 Company