



Membrane Technologies

# Certificate of Quality

The Hydrophobic PVDF filter has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiVent VF-γ Hydrophobic PVDF Membrane Filters**

Catalog No. : IVFX0801BBXX309  
Type : IVF-S  
Pore Size : 0.2 μm  
Lot Number : IV8467G  
Ster. No. : R012  
Expiry Date : 2019 - 07

### **SPECIFICATION**

Membrane : Hydrophobic PVDF  
Housing : Polypropylene  
Filter Diameter : 37 mm  
Effective Filtration Area (Nominal) : 10 cm<sup>2</sup>  
Burst pressure : > 8 Kg/cm<sup>2</sup>  
Sterilization : Pre sterilized by Gamma Irradiation

### **LOT RELEASE CRITERIA**

The above lot meets the following lot release criteria:

**100% Integrity Tested** : The filter has been tested for integrity by Bubble Point Test using 50% IPA/Water solution. Bubble point was: ≥ 18 psi (1.24 Bar)

**Air Flow Rate** : 10 lpm @ 1.0 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.

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

### **VALIDATED FOR**

**Bacterial Endotoxin Levels** : Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test.

**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).

### **PRECAUTIONS**

1. During handling, avoid contamination of outlet.
2. If pressure required to maintain the required flow becomes too high, the filter unit should be changed.

### **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

Issue Date: 24-Jul-17

### **Advanced Microdevices Pvt. Ltd.**

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