

# Certificate of Quality

The Polyethersulfone Membrane Vacuum Filter Device has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiVac KL- $\gamma$ PES Membrane Vacuum Filter Device**

Catalog No. : AKLX3101D10X302  
Type : AVKL-S  
Pore Size : 0.2  $\mu$ m  
Lot Number : AK8827G  
Ster. No. : R011  
Expiry Date : 2019 - 07

### **SPECIFICATIONS**

#### Materials of Construction

- Filter Membrane : Polyethersulfone
- Filter Housing : Polypropylene
- Receiver : Polystyrene

Filtration Area (Nominal) : 100 cm<sup>2</sup>

Maximum Operating Temperature : 45 °C

Sterilization : Pre sterilized by Gamma Irradiation

### **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:  $\geq$  16 psi (1.10 Bar)

#### **Water Flow Rate**

:  $\geq$  1.4 lpm @ Vacuum of 500 mm of Hg @ 27 °C

#### **Microbial Challenge Test**

: Retains  $\geq 10^7$  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 USP <71>.

### **VALIDATED FOR**

#### **Bacterial Endotoxin Levels**

: Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) test.

#### **Biosafety**

: Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

#### **Cytotoxicity**

: Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.

#### **Extractable**

: Within limits as specified in USP.

### **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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