

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

## **AseptiCap KL-γ PES Membrane Filters**

Catalog No. : VKLX1002SSRX102  
Type : VKL  
Pore Size : 0.45 μm  
Lot Number : IK9564K  
Manufacturing Date : 2024 - 11  
Expiry Date : 2029 - 11

### **SPECIFICATION**

Membrane : Polyethersulfone  
Housing : Polypropylene  
Filter Diameter : 50 mm  
Effective Filtration Area (Nominal) : 20 cm<sup>2</sup>  
Burst pressure : > 8 Kg/cm<sup>2</sup>  
Sterilization : Can be sterilized by Gamma Irradiation upto 50 kGy

### **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 purified water. Bubble point was: ≥ 30 psi (2.07 Bar)

**Typical Water Flow Rate** : 450 ml/min @ 0.70 kg/cm<sup>2</sup> @ 27 °C

### **VALIDATED FOR**

**Bubble point (50% IPA)** : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 10 psi (0.69 Bar)

**Microbial Retention** : Retains microbial challenge of *S. marcescens* (ATCC 14756).

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

**Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".

**Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).

**Extractable** : Within limits as specified in USP.

**Oxidizable matter** : Passes test as per USP.

**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>.

**Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)(1)(i).

**Total Organic Carbon** : Meets USP <643> limit of 500 ppb for total organic carbon after flushing specified volume of water for injection.

**Conductivity** : Meets USP <645> limit of 1.3 μS/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

### **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.

T. No.: COQ/ILF/007-03



Head of Quality Assurance

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