

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

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

Catalog No. : IKSX1001BBRX101  
Type : IKS  
Pore Size : 0.2 μm (0.45 μm + 0.2 μm)  
Lot Number : IK9224L  
Manufacturing Date : 2024 - 12  
Expiry Date : 2029 - 12

### **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**

**100% Integrity Tested** : The filter has been tested for integrity by Bubble Point Test using purified water. Bubble point was: ≥ 50 psi (3.44 Bar)  
**Typical Water Flow Rate** : 175 ml/min @ 0.70 kg/cm<sup>2</sup> @ 27 °C  
**Microbial Challenge Test** : Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

### **VALIDATED FOR**

**Bubble point (50% IPA)** : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 18 psi (1.24 Bar)  
**Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.  
**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).  
**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.  
**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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