

The Hydrophilic PVDF Membrane filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiCap WL-γ Hydrophilic PVDF Membrane Filters**

Catalog No. : IWLX0601MNXX304  
Type : IWL-S  
Pore Size : 0.2 μm  
Lot Number : IV9594L  
Ster. No. : R5564  
Date of Sterilization : 2024 - 12  
Expiry Date : 2026 - 12

### **SPECIFICATION**

Membrane : Hydrophilic PVDF  
Housing : Polypropylene  
Filter Diameter : 25 mm  
Effective Filtration Area (Nominal) : 5 cm<sup>2</sup>  
Burst pressure : > 14 Kg/cm<sup>2</sup>  
Sterilization : Pre sterilized by Gamma Irradiation at ≥ 25 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 DI water. Bubble point value with DI water was: ≥ 50 psi (3.44 Bar)

**Typical Water Flow Rate** : 30 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)

**Sterility** : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10<sup>-6</sup> in accordance with ISO 11137.

**Bacterial Endotoxin** : Filtrate meets the USP requirements for Sterile WFI of ≤ 0.25 EU/ml as determined 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>.

**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).

**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/018-02



Head of Quality Assurance

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