

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

## **AseptiCap WS Hydrophilic PVDF Membrane Filters**

Catalog No.	: IWSX0601MLXX204
Type	: IWS-S
Pore Size	: 0.2 µm (0.45 µm + 0.2 µm)
Lot Number	: IV55271
Ster. No.	: 111
Expiry Date	: 2020 - 09

### **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 with EO

### **LOT RELEASE CRITERIA**

The above lot meets the following lot release criteria:

<b>100% Integrity Tested</b>	: The filter has been tested for integrity by Bubble Point test using DI water. Bubble point value with DI water was: $\geq 50$ psi (3.44 Bar) The filter is also certified for integrity by Bubble point test using 50% IPA/Water solution. Bubble point with 50% IPA/Water solution is $\geq 16$ psi (1.10 Bar)
<b>Water Flow Rate</b>	: $\geq 25$ ml/min @ 0.70 kg/cm <sup>2</sup> @ 27 °C
<b>Microbial Challenge Test</b>	: Retains $\geq 10^7$ organisms/cm <sup>2</sup> of <i>B. diminuta</i> ATCC 19146 challenge as per ASTM F838-05 methodology.
<b>Sterility</b>	: Samples passed the sterility test in accordance with USP <71>.
<b>VALIDATED FOR</b>	
<b>Bacterial Endotoxins</b>	: Filtrate meets the USP requirements for Sterile WFI of $\leq 0.25$ EU/ml as determined by Limulus Amebocyte Lysate (LAL) test.
<b>Biosafety</b>	: Passes Biological Reactivity Tests, <i>In Vivo</i> for Class VI plastic as described in USP <88>.
<b>Cytotoxicity</b>	: Passes Biological Reactivity Tests, <i>In Vitro</i> as described in USP <87>.
<b>Indirect Food Additives</b>	: Passes as per FDA 21CFR 177.1520(a)1(i).
<b>Particle Release</b>	: Passes test as per USP <788>, "Particulate matter in Injections".
<b>Fiber Release</b>	: 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

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**An ISO 9001 Company**