

# Certificate of Quality

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

## AseptiPrime KS-γ PES Membrane Capsule Filters

Catalog No. : DKX95236AARX101  
 Type : DK  
 Pore Size : 0.1 μm (0.3 μm + 0.1 μm)  
 Lot Number : DK9564H SI.No. 052  
 Manufacturing Date : 2024 - 08  
 Expiry Date : 2029 - 08

### SPECIFICATION

<b>Length</b>	2"
<b>Filter Media</b>	Polyethersulfone Membrane
<b>Drainage Layers</b>	Polyester
<b>Housing</b>	Polypropylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Maximum Operating Temperature</b>	80 °C @ < 2 Kg/cm <sup>2</sup>
<b>Sterilization</b>	Can be sterilized by Gamma Irradiation upto 50 kGy

### LOT RELEASE CRITERIA

#### 100% Integrity Tested

: The Capsule filter has been tested for integrity by Air Diffusion Flow Test and Bubble Point Test using purified water.  
 Diffusion flows were: ≤ 4.0 ml/min @ 3.52 kg/cm<sup>2</sup>  
 Bubble point was: ≥ 65 psi (4.48 Bar).

#### Typical Water Flow Rate

: 650 ml/min @ 0.14 Kg/cm<sup>2</sup> @ 27 °C

#### Microbial Challenge Test

: Retains ≥ 10<sup>7</sup> organisms/cm<sup>2</sup> of *Acholeplasma laidlawii* (ATCC 23206).

### VALIDATED FOR

#### Bubble point (50% IPA)

: The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 26 psi (1.79 Bar)

#### Bacterial Endotoxin

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

#### 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).

#### 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.

### 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/CAP/002-05



Head of Quality Assurance

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