

Certificate of Quality

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

AseptiCap KS Polyethersulfone Membrane Filter

Catalog No. : IKS10636MNXX104
Type : IKS
Pore Size : 0.1 μm (0.2 μm + 0.1 μm)
Lot Number : IK9977G

SPECIFICATION

Membrane : Polyethersulfone
Housing : Polypropylene
Filter Diameter : 25 mm
Effective Filtration Area (Nominal) : 5 cm²
Burst pressure : > 14 Kg/cm²

LOT RELEASE CRITERIA

100% Integrity Tested : The filters have been tested for integrity by Bubble Point Test using 50% IPA/Water solution.
Bubble point was: \geq 31 psi (2.14 Bar).

Water Flow Rate : \geq 15 ml/min @ 0.70 kg/cm² @ 27 °C

VALIDATED FOR

Bacterial Endotoxin Levels : Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amoebocyte 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).

Extractable : Within limits as specified in USP.

Oxidizable matter : Passes test as per USP.

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