

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

ClariPro GK PES Membrane Prefilter

Catalog No. : IGKX0604MNXX104
Type : IGK
Pore Size : 0.5 µm (Nominal)
Lot Number : IK8997G

SPECIFICATION

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

LOT RELEASE CRITERIA

The above lot meets the following lot release criteria:

100% Integrity Tested : The filters has been tested for integrity by Bubble Point Test using purified water. Bubble point was: ≥ 10 psi (0.69 Bar)

Water Flow Rate : ≥ 300 ml/min @ 0.70 kg/cm² @ 27 °C

VALIDATED FOR

Sterilization : Maintains integrity after 5 autoclaving cycles at 121 °C of 30 minutes each.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

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