



Membrane Technologies

Certificate of Quality

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

ClariPro GK-γ PES Membrane Filters

Catalog No. : IGKX1001MMXX302
Type : IGK-S
Pore Size : 0.2 μm (Nominal)
Lot Number : IK5984L
Ster. No. : R2234
Date of Sterilization : 2024 - 12
Expiry Date : 2026 - 12

SPECIFICATION

Membrane : Polyethersulfone with Microglassfiber Prefilter
Housing : Polypropylene
Filter Diameter : 50 mm
Effective Filtration Area (Nominal) : 20 cm²
Burst pressure : > 8 Kg/cm²
Sterilization : Pre sterilized by Gamma Irradiation at ≥ 25 kGy

LOT RELEASE CRITERIA

100% Integrity Tested : The filter has been tested for integrity by Bubble Point Test using purified water. Bubble point was: ≥ 30 psi (2.07 Bar)
Typical Water Flow Rate : 300 ml/min @ 0.70 kg/cm² @ 27 °C

VALIDATED FOR

Bubble point (50% IPA) : The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point ≥ 10 psi (0.69 Bar)
Sterility : The sterilization process has been validated to assure Sterility Assurance Level (SAL) of 10⁻⁶ in accordance with ISO 11137.
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.

T. No.: COQ/ILF/009-04

Head of Quality Assurance

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An ISO 9001 Company