

Certificate of Quality

The Polyethersulfone membrane syringe filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

Polyethersulfone Membrane Syringe Filters

Catalog No.	: SYPL0302MNXX204
Type	: SY13PL-S
Pore Size	: 0.45 µm
Lot Number	: SK7757G
Ster. No.	: 045
Expiry Date	: 2020 - 07

SPECIFICATION

Membrane	: Polyethersulfone
Housing	: Polypropylene
Filter Diameter	: 13 mm
Filtration Area	: 0.8 cm ²
Burst pressure	: > 14 Kg/cm ²
Hold up volume	: < 20 µl
Sterilization	: Pre sterilized with EO

QUALITY ASSURANCE LOT RELEASE CRITERIA

Each lot has been sampled, tested and released by the Quality Assurance Department for the following characteristics:

- Integrity
- Flow Rate Performance
- Burst Pressure
- Leakage Test
- Retention: Microbial Challenge test
- Non Pyrogenicity: LAL Test
- Sterility

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).

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

Issue Date: 24-Jul-17

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An ISO 9001 Company