

# 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.	: SYKG0302MNXX204
Type	: SY13KG-S
Pore Size	: 0.45 µm
Lot Number	: SK8807G
Ster. No.	: 015
Expiry Date	: 2020 - 07

### SPECIFICATION

Membrane	: Polyethersulfone with Multilayer Glassfiber Prefilter
Housing	: Polypropylene
Filter Diameter	: 13 mm
Filtration Area	: 0.8 cm <sup>2</sup>
Burst pressure	: > 14 Kg/cm <sup>2</sup>
Sterility	: 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**