

Certificate of Quality

The Nylon-66 membrane syringe filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations.

Nylon-66 Membrane Syringe Filters

Catalog No.	: SYNN0601MNXX204
Type	: SY25NN-S
Pore Size	: 0.2 µm
Lot Number	: SN8898B
Ster. No.	: 054
Expiry Date	: 2021 - 02

SPECIFICATION

Membrane	: Nylon-66
Housing	: Polypropylene
Filter Diameter	: 25 mm
Filtration Area	: 4.15 cm ²
Burst pressure	: > 14 Kg/cm ²
Hold-up volume	: < 50 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 by Bubble point Test using DI water
Bubble point was: ≥ 50 psi (3.44 Bar)
- Flow Rate Performance
- Burst Pressure
- Leakage Test
- Retention: Microbial Challenge test as per ASTM F838-05 methodology

VALIDATED FOR

- 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

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An ISO 9001 Company