

Certificate of Quality

The Nylon-66 membrane filter device has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

AseptiCap NS Nylon-66 Membrane Filters

Catalog No. : INS51002MMXX102
Type : INS
Pore Size : 0.45 µm
Lot Number : IN8467G

SPECIFICATION

Membrane : Nylon-66
Housing : Polypropylene
Filter Diameter : 50 mm
Effective Filtration Area (Nominal) : 20 cm²
Burst pressure : > 8 Kg/cm²

LOT RELEASE CRITERIA

100% Integrity Tested : The filter has been tested for integrity by Bubble point test using DI water. Bubble point value with DI water was: ≥ 30 psi (2.07 Bar)
The filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.
Bubble point with 50% IPA/Water solution is ≥ 11 psi (0.76 Bar)

Water Flow Rate : ≥ 200 ml/min @ 0.70 kg/cm²

Microbial Challenge Test : Retains ≥ 10⁷ organisms/cm² of Serratia Marcescens ATCC 14756 challenge.

VALIDATED FOR

Extractable : Within limits as specified in USP.

Oxidizable Matter : Passes test as per USP.

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. INLET is marked on the device. Filtration should be done in proper direction.
2. During handling, avoid contamination of outlet.
3. 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