

Certificate of Quality

The Nylon Membrane Vacuum Filter Device has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

***AseptiVac NS* Nylon Membrane Vacuum Filter Device**

Catalog No. : ANS53102DXXG108
Type : AVNS
Pore Size : 0.45 µm (0.8µm + 0.45µm)
Lot Number : AN0128G

SPECIFICATIONS

Materials of Construction

- Filter Membrane : Nylon-66
- Filter Housing : Polypropylene
- Funnel : Polypropylene

Filtration Area (Nominal) : 100 cm²

Maximum Operating Temperature : 45 °C

LOT RELEASE CRITERIA

100% Integrity Tested : The filter has been tested for integrity by Bubble Point Test using 50% IPA/Water solution. Bubble point was: ≥ 11 psi (0.76 Bar)

Water Flow Rate : ≥ 2.0 lpm @ Vacuum of 500 mm of Hg @ 27 °C

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

VALIDATED FOR

Bacterial Endotoxin Levels : Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) test.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

Extractable : Within limits as specified in USP.

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: 30-Nov-18

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An ISO 9001 Company