

Certificate of Quality

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

AseptiVent TF Hydrophobic PTFE Membrane Filters

Catalog No. : ITFX1001BBXX102
Type : ITF
Pore Size : 0.2 µm
Lot Number : IT8567G

SPECIFICATION

Membrane : Hydrophobic PTFE
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 70% IPA/Water solution. Bubble point was: ≥ 22 psi (1.52 Bar)

Water Intrusion Rate : < 0.05 ml/min @ 30 psi (2.07 bar)

Water Breakthrough Pressure : ≥ 30 psi (2.07 bar)

Air Flow Rate : ≥ 10 lpm @ 0.25 kg/cm²

Microbial Challenge Test : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology..

VALIDATED FOR

Bacterial Endotoxin Levels : Aqueous extracts exhibit < 0.5 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test.

Heat Stability : Maintains integrity after 30 autoclaving cycles at 121 °C of 30 minutes each.

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