

Certificate of Quality

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

AseptiVent VF- γ Hydrophobic PVDF Membrane Filters

Catalog No. : IVFX0801BBRX102
Type : IVF
Pore Size : 0.2 μ m
Lot Number : IV8804L
Manufacturing Date : 2024 - 12
Expiry Date : 2029 - 12

SPECIFICATION

Membrane : Hydrophobic PVDF
Housing : Polypropylene
Filter Diameter : 37 mm
Effective Filtration Area (Nominal) : 10 cm²
Burst pressure : > 8 Kg/cm²
Sterilization : Can be sterilized by Gamma Irradiation upto 50 kGy

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: \geq 18 psi (1.24 Bar)

Typical Air Flow Rate : 10 lpm @ 1.0 kg/cm²

Microbial Challenge Test : Retains $\geq 10^7$ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

VALIDATED FOR

Bacterial Endotoxin : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.

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).

Particle Release : Passes test as per USP <788>, "Particulate matter in Injections".

Fiber Release : Complies with FDA 21CFR 210.3(b)(6).

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.

T. No.: COQ/ILF/020-00



Head of Quality Assurance

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An ISO 9001 Company