

# Certificate of Quality

The Polyethersulfone membrane Vacuum filtration device has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## Polyethersulfone Membrane Vacuum Filtration Device

Catalog No. : VFPX1102XXXX212  
Type : VF75PS-S  
Pore Size : 0.45 µm  
Lot Number : VK9977G  
Ster. No. : 011  
Expiry Date : 2020 - 07

### SPECIFICATION

Membrane : Polyethersulfone  
Plastic Components  
    Cup : Acrylic  
    Base : Polypropylene  
Filter Diameter : 75 mm  
Sterilization : Pre sterilized with EO

### LOT RELEASE CRITERIA

**Water Flow Rate** :  $\geq 450$  ml/min at Vacuum of 450 mm of Hg @ 27 °C  
**Microbial Challenge Test** : Retains  $\geq 10^7$  organisms/cm<sup>2</sup> of *Serratia marcescens* ATCC 14756 challenge.  
**Sterility** : Samples passed the sterility test in accordance with U.S Pharmacopoeia.

### VALIDATED FOR

**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).

### 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**