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Certificate of Quality Assurance

Product Information

Part Number: QPPESFU250250022
Lot Number: 180316063
Pore Size: 0.22µm
Expiry Date: 2021.03.17

ISO 9001 Quality Standard

This product was manufactured in the Membrane Solutions facility whose Quality Management System is approved by an accredited registering body to the ISO 9001 Quality Systems Standard

Non-Fiber Releasing

This product was manufactured using the membrane which meets the criteria for "non-fiber" releasing filters as defined in 21 CFR 210.3 (b) (6)

Sterilization

This Product is gamma irradiate sterilization

Bacterial Endotoxin

This Product was determined by LAL test according to current USP. An extract from the product contained was equal to or less than 0.25EU/mL

Biosafety

This product meet the criteria of the USP<88>Biological Reactivity test for Class VI Plastics

Membrane Testing Criteria

Membrane Solutions certify that the membrane was tested according to:

Membrane Bubble Point Integrity

Products were tested according to an established procedure to determine the water bubble point of the product. The membrane bubble point of this lot is 50.8-66.7 psi.

Flow Rate

Products met a flow rate of 41.49-44.33 ml/min/cm²@-10psi test by deionised water at 25°C,
Products met a flow rate of 25.08-30.69 ml/min/cm²@-10psi test by 3.0% TSB solution at 25°C

Bacterial Retention

Products were demonstrated the following retention levels using ASTM method F838-05.

| Challenge Organism | LRV |
|---|-----|
| <i>Brevundimonas diminuta</i> (ATCC 19146) | 7 |

Tested By:  09-05-2018

QC Technician