



Certificate of Quality

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Product Information

Part Number: QPPESFU250500045
Lot Number: 180305015
Pore Size: 0.45µm
Expiry Date: 2021.03.17

ISO 9001 Quality Standard

The product was manufactured according to 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

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 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 23.9-26.1 psi

Flow Rate

Products met a flow rate of 55.7-63.3 ml/min/cm2@-10psi test by deionised water at 25°C,
Products met a flow rate of 49.07-55.2 ml/min/cm2@-10psi test by 3.0% TSB solution at 25°C

Tested By:  09-05-2018

QC Technician

Toll free: 1-866-528-4572

Fax: 1-732-412-4040

Website: www.membrane-solutions.com

Address: JP Morgan International Plaza Suite 650, 14241 Dallas Parkway, Dallas, TX, US