

## Pellicon® 2 Filter

Catalogue Number: P2B01MC25

Lot Number: xxxxxxxx

Membrane Type: PBXK

Membrane Area: 2.5 m<sup>2</sup>

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

### ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

### Materials

Membrane: Polyethersulfone

Screens: Polypropylene

Adhesives: Urethane

Toxicity: All parts in fluid paths were tested and meet the criteria of the USP Class VI Biological Tests for Plastics.

### 100% Integrity Tested in Manufacturing

Each unit must pass the Millipore Integrity Test based on air flow through the fully-wetted membranes of the filter.

### Quality Assurance Lot Release Criteria

Every unit is tested by Manufacturing and released by Quality Assurance to the following specifications:

#### Integrity

Each unit exhibited air flow through fully-wetted membranes less than or equal to 300 cc/min at 10 psig (0.7 bar) inlet pressure.

#### Pressure Drop

(For 2.5m<sup>2</sup> Maxi's, note that test is done on 0.5m<sup>2</sup> elements.)

Samples met a maximum pressure drop of 4-12 psi (0.3-0.8 bar) at 0.8 gpm (3.0 L/min) average cross flow of clean water.

### Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

#### USP Oxidizable Substances

Effluent was negative after an RO water flush.

#### Gravimetric Extractables

The extractables level was equal to or less than 1500mg/m<sup>2</sup> after an RO water flush



Peter Eichert  
Quality Manager

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