

# Pellicon® 2 Filter

Catalogue Number: P2B030A25  
Lot Number: C9KN16679  
Membrane Type: PBTK  
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 90 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 11-20 psi (0.8-1.4 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

Affluent 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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