

# Pellicon® 2 Filter

Catalogue Number: P2B050A01  
Lot Number: C9BN71709  
Membrane Type: PBQK  
Membrane Area: 0.1 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 4 cc/min at 10 psig (0.7 bar) inlet pressure.

### Pressure Drop

Samples met a maximum pressure drop of 11.20 psi (0.8-1.4 bar) at 0.2 gpm (0.6 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

MILLIPORE

Millipore, Durapore and Pellicon are registered trademarks of Millipore Corporation.  
ISO is a registered trademark of the International Standards Organization.  
00099620PU Rev F 06/08