

## Pellicon® 2 Filter

Catalogue Number: P2B010A05

Lot Number: C9KN23518

Membrane Type: PBGC

Membrane Area: 0.5 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

Screening: 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 18 cc/min at 30 psig (2.1 bar) inlet pressure.

### Pressure Drop

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