

## Pellicon® 3 - 1.14 m<sup>2</sup> Cassette

Catalogue Number: P3C010C10

Lot Number: C7NN09460

Membrane NMWCO: 10 kD

Membrane Area: 1.14 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.

### 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.

### Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the device fabrication process. In-process controls are used to assure stability of the process.

### Materials

Regenerated Cellulose membrane, Polypropylene, Polyethylene, Stainless Steel, Thermoplastic elastomeric external seals, 3-4% Benzyl alcohol /20% glycerol/water

Millipore and Pellicon are registered trademarks of Millipore Corporation. ISO is a registered trademark of the International Standards Organization. ASTM is a registered trademark of the American Society for Testing and Materials P89837 Rev D 03/08

## 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 membranes fully-wetted with water less than or equal to:

- 60 cc/min at 30 psig (2.1 bar) inlet pressure.

### Pressure Drop

Each unit met a maximum pressure drop of 6-18 psi (0.4-1.2 bar) at 6.0 L/min average cross flow of clean water.

### Sealing

Each device is challenged at 100 psi air pressure.

### Quality Performance Criteria

This product was designed and tested to meet the following performance specifications.

### Maximum Operating Temperature and Pressure:

- 80 psi TMP at 40°C
- 40 psi TMP at 50°C

### Maximum Reverse Pressure Exposure:

- 30 psi TMP at 25°C

## Design Criteria

This product was designed and manufactured to meet the following specifications.

### Gravimetric Extractables

The NVR extractables level was equal to or less than 1500 mg/m<sup>2</sup> after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

### Class VI Toxicity Testing

All parts in fluid paths were tested and meet the criteria of the USP <88> Biological Reactivity Tests for Class VI Plastics.



Peter Erchert  
Quality Manager

MILLIPORE