

## **Pellicon® 3 - 0.11 m<sup>2</sup> Cassette**

Catalogue Number: P3C030C01

Lot Number: C9AN54675GL

Membrane NMWCO: 30 kD

Membrane Area: 0.11 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, Thermoplastic elastomeric external seals, 3-4% Benzyl alcohol /20% glycerin/water

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## **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:

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

### **Pressure Drop**

Each unit met a maximum pressure drop of 5-14 psi (0.3-1.0 bar) at 600 mL/min average cross flow of clean water.

### **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 Eichert  
Quality Manager

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