

## **Prep/Scale® TFF Cartridge**

Catalogue Number: CDU-006TG

Lot Number: C9KN22976

Membrane Type: PTGC

Membrane Area: 6 ft<sup>2</sup>

### **Good Manufacturing Practices**

This product was manufactured in a Millipore facility which meets or exceeds FDA Device Good Manufacturing Practice standards.

### **ISO 9000 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 9000 Quality Systems Standard.

### **Materials**

Membrane: Polysulfone

Screens: Polyethylene, Polypropylene

Central tube and housing: Polysulfone

Adhesive: Urethane

Toxicity: All parts in the fluid path were tested and meet the criteria for the USP Class VI Biological Test 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.

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### **Quality Assurance Lot Release Criteria**

Every unit was 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 66 cc/min at 20 psig (1.4 bar) inlet pressure.

#### **Housing Integrity**

Each unit met a housing leakage less than 1.0 cc/min following pressurization to 80 psig (5.5 bar).

#### **Pressure Drop**

Each module exhibited a maximum pressure drop of 8 psig (0.55 bar) at 1.2 - 1.8 gpm (4.5-6.8 L/min) average cross flow of clean water at an inlet feed pressure of 40 psi (2.8 bar).

### **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**

Effluent was negative after an RO water flush.

#### **Gravimetric Extractables**

The extractables level was equal to or less than 1500 mg per m<sup>2</sup> after an RO water flush.

#### **Hydraulic Stress**

Samples were tested and found to have a burst pressure of greater than 3X the maximum operating pressure of 80 psig (5.5 bar).



Peter Eicherl

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