

## Prostak™ MF Module

Catalogue Number: SK2P12ZE1

Lot Number: xxxxxxxxxx

Membrane Type: WPP

Membrane Area: 20ft<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 Testing 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 50 cc/min at 50 psig (3.4 bar) inlet pressure.

#### Housing Integrity

The module housing integrity was tested at 80 psi (5.5 bar) and found to be integral.

### 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.

#### Thermal and Hydraulic Stress

Samples steamed in place at 126 °C and 20 psi remained integral after 20 cycles.

*Lauren LeClair*

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Quality Manager

