

Prostak™ MF Module

Catalogue Number: SK2P484E0

Lot Number: C9ENT0037

Membrane Type: GVPP

Membrane Area: 20ff²

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 30 cc/min at 30 psig (2.1 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

Affluent 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.



Peter Eichert
Quality Manager

