

# Aervent™ Cartridge Filter

0.2 µm Rated

Catalogue Number: CTGR75S01

Lot Number: C6MN93515

## 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.

## Non-Fiber Releasing

This product was manufactured with a PTFE membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

## Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

## 100% Integrity Testing in Manufacturing

Each unit must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* HIMA bacterial challenge test.

## Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

### Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of  $1 \times 10^7$  CFU/cm<sup>2</sup> using HIMA methodology.

### USP Bacterial Endotoxins

A cartridge aqueous extract contains less than 0.5 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

### Integrity

Samples exhibited a bubble point equal to or greater than 16 psig (1103 mbar) in a 70/30% IPA/water mixture using nitrogen as the test gas at 23 °C.

Samples exhibited a nitrogen diffusional flow rate of less than or equal to 12 cc/min at 14 psig (966 mbar) in a 70/30% IPA/water mixture at 23 °C per 5-inch cartridge.

Samples exhibited a HydroCoir test value less than or equal to 0.38 mL/min per 5 inch cartridge at 38 psig (2620 mbar).

### Thermal and Hydraulic Stress

Samples were steamed in place at 145 °C and maintained integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 60 psid (4.1 bar).

### Air Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 2.8 psid (190 mbar) at an air flow rate of 50 SCFM (85 m<sup>3</sup>/hr), and 0 psig outlet air pressure at 23 °C per 5-inch cartridge.

## Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

### Toxicity

This product is non-toxic per the current USP General (Mouse) Safety Test.

### Gravimetric Extractables

The extractables level was equal to or less than 18 mg per 5-inch cartridge after 24 hours in a 70/30% IPA/water mixture at controlled room temperature.

### Multiple Sterilization Cycles

Integrity was maintained after 100 forward and 50 reverse steam-in-place cycles of 30 minutes at 145 °C.



Peter Fichert  
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