

## Aervent® Cartridge Filter

0.2 µm Rated

Catalogue Number: CTGR71TP1

Lot Number: C9HN12062

### 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.

### 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* ASTM® F838 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 ASTM F838 methodology.

#### USP Bacterial Endotoxins

A cartridge aqueous extraction 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 1.6 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 24 cc/min at 14 psig (966 mbar) in a 70/30% IPA/water mixture at 23° C per 10-inch cartridge.

Samples exhibited a HydroCarr test value less than or equal to 0.75 mL/min per 10-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 psia (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 1.05 psid (72.4 mbar) at an air flow rate of 50 SCFM (85 m<sup>3</sup>/hr), and 0 psig 0 (mbar) outlet air pressure at 23° C per 10-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 3.5 mg per 10-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 Eichert

Quality Manager



Millipore and Aervent are registered trademarks of Millipore Corporation. ASTM is a registered trademark of the American Society for Testing and Materials. ISO is a registered trademark of The International Organization for Standardization.

P35320 Rev H 03/09