

# Opticap<sup>®</sup> XL Capsule Filter with Milligard<sup>®</sup> Media

0.2 µm Nominal Rated

Catalogue Number: KW03A04TT3

Lot Number: C9KN35728

## 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 Millipore media combination 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.

## Indirect Food Additive

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.182.

## European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

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## Quality Assurance Lot Release Criteria

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

### USP Bacterial Endotoxins

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

### Structural Integrity

Samples from Milligard cartridges used in this lot were found to be integral as measured by an aerosol challenge test.

### Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 2.9 psid (200 mbars) at 2.0 gpm (7.6 L/min) with clean water at 23°C.

### USP Oxidizable Substances

Effluent was negative after a water flush of 1 L per autoclaved sample.

## Quality Performance Criteria

This product was assigned and manufactured to meet the following specifications:

### 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 25 mg per sample after 24 hours in ASTM<sup>®</sup> Type I reagent-grade water at controlled room temperature.

### Multiple Sterilization Cycles

Sample integrity was maintained after 3 autoclave cycles of 30 minutes at 121°C.



Peter Eichert  
Quality Manager

