# Lifegard™ Cartridge Filter

1.0 µm Nominal Rated
Catalogue Number: CP15M4S03
Lot Number: C9HN14516

### 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.

### Component Materials Toxicity

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

## Quality Assurance Lot Release Criteria

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

### USP Bacterial Endotoxins

A cartridge aqueous extraction contains less than 1.0 EU/mL as determined using the Limulus Amebocyte lysate (LAL) test.

### Structural Integrity

Samples were found to be integral as measured by an aerosol challenge test.

### Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 2.0 psid (140 mbar) at 5.0 gpm (19 L/min) per 4-inch cartridge with clean water at 23 °C.

### USP Oxidizable Substances

Effluent was negative after a water flush of 2 L per autoclaved 4-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 100 mg per 4-inch cartridge after 24 hours in ASTM Type 1 reagent-grade water at controlled room temperature.

### Multiple Sterlization Cycles

Integrity was maintained after 10 steam-in-place cycles of 30 minutes at 121 °C.

Peter Eichert
BioPharmaceutical Quality Manager

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