# Milligard® Cartridge Filter

1.2 µm Nominal Rated
Catalogue Number: CW1971S03
Lot Number: C9DN84786

## 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 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.

## 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 0.5 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 4.0 psid (276 mbar) at 10 gpm (38 L/min) per 10-inch cartridge with clean water at 23 °C.

## USP Oxidizable Substances

Effluent was negative after a water flush of 5 L per autoclaved 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 50 mg per 10-inch cartridge after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

## Multiple Sterilization 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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