

# Millipore Express® SHC Hydrophilic Cartridge Filter

0.5/0.2µm Rated

Catalogue Number: CHGEZ5TF3

Lot Number: xxxxxxxxxx

## 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.

## 100% Integrity Testing in Manufacturing

Each filter cartridge must pass the Millipore Integrity Test correlated to the *Brevundimonas diminuta* ASTM® F838 bacterial challenge test.

## Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the cartridge fabrication process. In-process controls are used to assure stability of the process.

## Alcohol Reference Test

Sterilizing-grade (0.2µm) hydrophilic Millipore Express SHC membrane is certified to a bubble point equal to or greater than 18.5 (1275 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

## 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 relative 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 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

### Integrity

Samples tested on an automated integrity tester exhibited a water bubble point equal to or greater than 58.0 psig (4000 mbar) with air at 23° C.  
Samples exhibited an air diffusional flow rate of less than or equal to 1.3.3 cc/min. per 5-inch cartridge at 40 psig (2758 mbar) in water at 23° C.

### Thermal and Hydraulic Stress

Samples were steamed at 135° C for 30 minutes and maintained integrity after a forward stress to 100 psid (6895 mbar) and a reverse stress to 30 psid (2068 mbar).

### Flow Rate and Pressure Drop

Cartridge samples met a maximum pressure drop of 6.1 psid (421 mbar) at 2 gpm (7.6 L/min) per 5-inch cartridge with clean water at 23° C.

### USP Oxidizable Substances

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 2 liter per autoclaved 5-inch cartridge.

### TOC/Conductivity

Samples exhibited less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm per USP <645> after autoclaving and a WFI water flush of 9.5 liters per 5-inch cartridge at 25° C.

## Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

### Multiple Sterilization Cycles

Cartridge integrity was validated for the following in-line steam cycles:

25 forward cycles, 30 min., 135° C at ≤ 5 psid (340 mbar) or 22 forward cycles, 30 min., 135° C at ≤ 5 psid (340 mbar) and 3 reverse cycles, 30 min., 135° C at < 1 psid (69 mbar) or 3 forward cycles, 30 min., 135° C at less than or equal to 15 psid (1000 mbar)

### Maximum Differential Pressure

Forward: 100 psid (6895 mbar) at 25° C  
25 psid (1700 mbar) at 80° C  
15 psid (1000 mbar) at 135° C

Reverse: 30 psid (2068 mbar) at 25° C  
< 1 psid (69 mbar) at 135° C

### Toxicity

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% Sodium Chloride extraction.

This product is non-cytotoxic per USP Cytotoxicity MEM Elution test.

### Indirect Food Additive

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

### Non-Fiber Releasing

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



Peter Eichert

Jaffrey Quality Manager



Brigitte Weber

Molsheim Quality Manager