

# Sterile Millex® Filter Unit

Pore Size Rating: 0.20 µm  
Catalogue Number: SLFG025LS  
Lot Number: R9MN39716  
Expiry Date: 2012 10  
Sterilization Date: 2009 10  
Membrane Type: Fluoropore(Hydrophobic PTFE)

## Good Manufacturing Practice

This product was manufactured in a Millipore Facility that meets FDA Device Good Manufacturing Practice Standards under the Quality System Regulation and ISO 13485 Standard for Medical Device production.

## CE Marking

Product is CE marked in accordance with EC directive 93/42/EEC 1993

## 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 ISO 9001 Quality Systems Standard.

## Component Materials Toxicity

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

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Rev 04/06

## Quality Assurance Lot Release Criteria

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

### Bacterial Endotoxins

An aqueous extraction from the unit contains less than or equal to 20 EU/Unit as determined using the Limulus Amebocyte Lysate (LAL) Test.

### Integrity

Each unit is air tested during the manufacturing process to ensure both membrane and housing integrity. Prior to release, samples are tested to meet a methanol bubble point specification of  $\geq 13$ psi and particle challenge tested by a method that correlates to the *Brevundimonas diminuta* HIMA bacterial challenge test.

### Housing Burst

Samples meet a minimum housing burst of 75 psi

### Air Flow Rate

Samples exhibit a minimum air flow rate greater than 1 l per minute at 1 psi

### Sterility

This product has been sterilized by Ethylene Oxide (EO) in a validated sterilization cycle according to ISO 11135 standard. Spore strips (*Bacillus atrophaeus* 10<sup>6</sup>) incorporated in the lot have been shown to be sterile. Maximum EO residue limits meet the U.S. Federal guideline for devices contacting blood (ex vivo).

## Quality Assurance Audit Criteria

This product was designed and manufactured to meet the following characteristics that are confirmed by testing on an audit basis.

### Toxicity

Non-toxic as per the current USP Mouse Safety Test.

### Downstream Particles

Samples show no more than 50 particles  $>10$  µm per unit.

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