

Sterile Millex® Filter Unit

Pore Size Rating:	0.20 µm
Catalogue Number:	SLFG025LS
Lot Number:	R9JN11074
Expiry Date:	2012 07
Sterilization Date:	2009 07
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.

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 ≥ 13 psi and particle challenge tested by a method that correlates to the *Bravuridinomas dimirinda* 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* 10⁶) 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.

Joe Bergin



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