Sterile Millex® Filter Unit

Pore Size Rating	0.22µm
Catalogue Number	SLGS033SB
Lot Number	0000225581
Expiry Date	2026 03
Sterilization Date	2023 03
Membrane Type	MF-Millipore™ (Mixed Cellulose Esters)

Good Manufacturing Practice

This product was manufactured in a Merck Millipore Facility that meets the ISO® 13485 Standard for Medical Device production.

CE Marking

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

ISO® 9001 Quality Standard

This product was manufactured in a Merck 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 for biocompatibility and meet the requirements for ISO® 10993 (External communicating devices, blood path indirect, less than or equal to 24 hour contact duration) and the current USP Class VI Biological Test for Plastics.

EO Residuals

Maximum EO residue limits meet the U.S. Federal guideline for devices contacting blood (ex vivo) and ISO® 10993-7.

Millex is a registered trademark of Merck KGaA, Darmstadt, Germany.
MF Millipore is a trademark of Merck KGaA
ISO is a trademark of the International Standards Organisation

Quality Assurance Lot Release Criteria

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

Integrity

Each unit is tested during the manufacturing process to ensure defect free membrane. Prior to release, samples are tested to meet a water bubble point specification of ≥ 50 psi (3.45 bar) and particle challenge tested by a method that statistically correlates to the *Brevundimonas diminuta* ASTM bacterial challenge test.

Housing Burst

Samples meet a minimum housing burst of 150 psi (10.34 bar)

Water Flow Rate

Samples exhibit a water flow rate greater than or equal to 75ml per minute at 30 psi (2.07 bar) with 0.22µm filtered RO water at 25°C

Sterility

This product has been sterilized by Ethylene Oxide (EO) in a validated sterilization cycle according to ISO 11135 standard. Spore strips (*Bacillus atrophaeus* 10^6 minimum spore count) incorporated in the lot have been shown to be sterile.

Quality Assurance Audit Criteria

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

Downstream Particles

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

Bioburden

Samples show no more than 50 microorganisms per unit prior to sterilization.

Bacterial Endotoxins

An aqueous extraction from the unit contains less than or equal to 2.15 EU/Unit as determined using the Limulus Amebocyte Lysate (LAL) Test.

Elaine Kennedy

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Rev 06/21

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Certificate of Quality

The purpose of this certificate is to provide precise information on the quality characteristics and acceptance criteria which support the high standards of quality and reliability built into our products.

We certify that the product described within meets the following criteria.

The M mark is a trademark of Merck KGaA, Darmstadt, Germany.
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