

Sterile Millex® Filter Unit

Pore Size Rating: 0.45 µm
Catalogue Number: SLHA0033SS
Lot Number: R9JN25226
Expiry Date: 2012 07
Sterilization Date: 2009 07
Membrane Type: MF-Millipore
(Mixed Cellulose Esters)

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 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.

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 2.15 EU/Unit as determined using the Limulus Amoebocyte Lysate (LAL) Test.

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 ≥ 30 psi (2.07 bar) and particle challenge tested by a method that statistically correlates to the *Brevundimonas diminuta* HIMA 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 180 ml 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* 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 \times 10 µm per unit.

Bioburden

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

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Rev 04/06

