Steritop® Filter Unit

Catalogue Number:	S2GPT02RE
Membrane Type:	Millipore Express® PLUS (PES)
Pore Size Rating:	0.22µm
Lot Number:	MP223402G2
Sterilization Date:	AUG 2022
Expiry Date:	AUG 2025

Good Manufacturing Practice

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

ISO® 9001 Quality Standard

This product was manufactured in Facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

Component Materials Toxicity

Membranes were tested and meet the criteria for the current USP Class VI Biological Test for Plastics. Fluid path component materials were tested and determined to be non-cytotoxic in accordance with the current USP

20261081 Rev: 2.0

Quality Assurance Lot Release Criteria

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

Integrity

Each lot is air tested for reverse burst at 30" water during the manufacturing process to ensure both membrane and housing integrity.

Filter Flow Rate

Samples exhibit an initial flow time of not more than 52 seconds to filter 500ml of water at 25"Hg vacuum

Sterility

This product has been sterilized by GAMMA irradiation in a validated sterilization cycle and meets an established dose as per AAMI validation guidelines.

Membrane Bubble Point

Samples were tested according to an established procedure to determine the IPA bubble point of this product

Minimum observed IPA bubble point is 20 psi

Quality Assurance Audit Criteria

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

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

Sterilization Validation

Gamma Irradiation dose is confirmed on a quarterly basis according to AAMI practices and recommendations.

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration 1×10^7 cfu per cm^2 using HIMA methodology

Thomas Brackett
Quality Manager

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Millipore®

Certificate of Quality

The purpose of this certificate is to provide precise information on the quality and 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.