

Stericup® Quick Release

Quality Assurance Lot Release Criteria

Quality Assurance Audit Criteria

Catalogue Number:	S2GPPU01RE
Membrane Type:	Millipore Express® PLUS (PES)
Pore Size Rating:	0.22µm
Lot Number:	MP243106G2
Sterilization Date:	AUG 2024
Expiry Date:	AUG 2027

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.

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

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.

Filter Flow Rate

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

Sterilization Validation

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

ISO® 9001 Quality Standard

Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

Sterility

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

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration 1×10^7 cfu per cm² using HIMA methodology

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

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

Thomas Brackett
Quality Manager



Stericup, Millipore Express and Millipore are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

© 2019 Merck KGaA, Darmstadt, Germany and/or its affiliates. All rights reserved.

20261078 Rev. 2.0



EMD Millipore Corporation
400 Summit Drive
Burlington, MA 01803 USA



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.



The M is a trademark of Merck KGaA, Darmstadt, Germany
Millipore is a registered trademark of Merck KGaA, Darmstadt, Germany.
2017 EMD Millipore Corporation, Billerica, MA 01821 U.S.A.
All rights reserved.
P35690 Ver. 11.0 01/2018



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.