Corning Incorporated Life Sciences

Registered ISO 9001:2008

Certificate of Compliance

431206 Catalog Number:

Lot Number: 28204003

Product Description: Corning® 1 Liter filter system, cellulose acetate membrane, 0.45 µM pore size,

500 mL funnel

Expiration Date:

An expiration date exists for this product. Please refer to the case label and the filter funnel for the expiration date for this product.

Component Materials:

Funnel, Funnel Lid & -Receiver/Storage

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and

closures.

Bottle Funnel Adapter, Hose -

Connector & Plug

Virgin High Density Polyethylene, meets USP, Class VI requirements for plastic containers and closures. Heavy metal free (meets CONEG req.) color concentrate.

Seal Cap

Membrane Cellulose Acetate, 0.45 µM pore size Filter Plug Cellulose Acetate

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization. Sterility Assurance Level: SAL 10⁻⁵

The product has been tested and has met the criteria established in the Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Parenteral Drugs, Biological Products and Medical Devices (FDA, December, 1987).

Results: less than 0.1 EU/mL

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure: Results: Leak Test Pass Visual Attributes Pass **Pass** Packaging

Wendy Latsch

Wendy Loitsch Quality Manager

Rev No: 4