

Catalog Number: 3528

Product Description: Corning® Disposable 500ml Spinner Flask, Side Arm Accessory, with MPC quick connect, GL45 thread, 0.2um membrane

Component Materials:

- Cap - Virgin High Density Polyethylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets CONEG requirements) color concentrate.
- Filter - 0.2um PTFE membrane, meets *USP, Class VI* requirements for plastic containers and closures.
- Tubing - Chemically resistant, heat sealable, thermoplastic elastomer, meets *USP, Class VI* requirements for plastic containers and closures
- MPC Quick Connect - Medical Grade PC, meets *USP, Class VI* requirements.

Product Dimensions:

- Cap Diameter - 45mm (1.77in) Cap Height - 25.3mm (1.0in)
- Tolerances - +/- .050in

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization* Sterility Assurance Level: SAL 10⁻⁶

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Non-Pyrogenic:

Tested and met the criteria established in the current version of ANSI/AAMI 72, Bacterial Endotoxins – Test methodologies, routing monitoring, and alternatives to batch testing” and USP <85>, “Bacterial Endotoxins Test”. The acceptance level for product is ≤ 0.25 EU / ml or ≤ 10 EU / device.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes: Visual examination of the product.

Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.