

Catalog Number: 431446

Product Description: 2 L Erlenmeyer Flask Aseptic Connector, 2 Port, 1/8" Diptube, 0.2 um Vent, 1/8" C-Flex w/Male LL

Component Materials:

- Cap - Virgin Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures. Heavy metal free (meets *CONEG* requirements) color concentrate.
- Tubing - C-flex thermoplastic elastomer, meets *USP, Class VI* requirements for Biological Test for Plastics.
- Filter - 50mm filter with 0.2 µM pore PVDF membrane, meets USP Biological Reactivity Test, *InVivo <88>*.
- Diptube - Polypropylene, meets USP, Class VI
- Male Luer Lock and Cap - Polypropylene, meets USP, Class VI

Product Dimensions:

Overall Length - 47.5 +/- 1.0 in. Outer Diameter of cap - 2.13 +/- 0.05 in.

Sterilization:

This product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (TIR 33) *Sterilization of healthcare 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 revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

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 manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Revision Date:

04-14-20

Rev No: 5