



TriForest Enterprises, Inc.

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## Certificate of Quality

TriForest Labware certifies that this product meets the following criteria

### Description of Product:

Polycarbonate Erlenmeyer/Shaker  
Culture flask  
125ml, 250ml, 500ml, 1000ml, 2000ml sizes  
Catalog Numbers: FPC0125S, FBC0125S  
FPC0250S, FBC0250S, FPC0500S, FBC0500S  
FPC1000S, FBC1000S, FPC2000S, FBC2000S  
Pore Size: 0.22um PTFE membrane on the cap.  
Lot Number: 980101

### PRODUCT CRITERIA

**Non-Toxin Leaching Resin:** This product was manufactured using GE LEXAN 104-112 resin, FDA compliant

### Component Materials Toxicity

All component materials have been tested and met the requirements for United States Pharmacopoeia (USP) Class VI Biological Test for Plastics, current edition. The materials also pass the requirements of the MEM elution Cytotoxicity Procedure utilizing WI 38 or MRC5 cell lines. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.1640.

### Heavy Metals

The resins used in the manufacture of TriForest Disposable Erlenmeyer flasks do not require reporting under the Superfund Amendment and Reauthorization Act (SARA) Title III Section 313. They would pass Toxicity Characteristic Leaching Procedure (TCLP) testing.

### Membrane Gravimetric Extractable

The extractable level of the membrane was less than **1.00** weight percent of the membrane.

### LOT CRITERIA

The manufacturing lot was sampled, tested and released by Quality Assurance for the following characteristics:

### Sterilization

Product has been gamma irradiated and dosimetrically released based upon U.S. Association for the Advancement of Medical Instrumentation (AAMI) Recommended practices. Refer to the radiation certificate.

### Pyrogens

An extract from the lot contained < **0.005** EU/ml per the Limulus Amebocyte Lysate (LAL) test method in the FDA *Guidelines on Validation Of The Limulus Amebocyte Lysate Test As an End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, And Medical Devices*, December 1987.

### AUDIT CRITERIA

Audit criteria tests are conducted on a routine basis as Appropriate for each product configuration manufactured.

### Bioburden

Samples were evaluated to determine the viable microbial Bioburden of the product prior to sterilization.

### Sterilization Validation

Gamma irradiation is validated on a quarterly basis utilizing the recommended practices of AAMI.

**All TriForest Labware is for research use only, not for invitro diagnosis or parenterals.**

*Devin Chiu*

Quality Assurance Manager