

# Quality Certificate



**229010B**

## **10mL Serological Pipets Individually Wrapped Pipets, Sterile**



Lot Number: 2108062  
Expiration Date: 08/06/2024

This product is assembled in accordance with ISO 9001:2015 and ISO 13485:2016 quality management systems in a class 100,000 clean room.

### **Component Materials**

Virgin Polystyrene: meets USP, Class VI requirements.

### **Sterilization Assurance Level**

SAL  $10^{-6}$

This lot has been gamma irradiated and dosimetrically released. Procedures for determining the dosage comply with ANSI/AAMI/ISO 11137.

### **Cytotoxicity**

All material resins are qualified using USP and/or ISO 10993 standards for cytotoxicity and have been shown to be non toxic.

### **Non-pyrogenic**

Products have been validated to have less than 0.1 EU/mL.

### **RNase/DNase Testing**

This product has been tested and is free of any detectable RNase/DNase contamination.

### **Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy**

CELLTREAT Scientific Products controls materials used in manufacturing processes such that no known animal derivative components are used in the manufacture of its products. Materials and processing meet EMEA/410/01-Rev3, Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.

### **Quality Control Testing**

Representative Samples have been selected and inspected according to ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection for Attributes. This lot has passed inspection.

### **Quality Control Testing**

CELLTREAT serological pipets are accurate to +/- 2% at full volume.

### **Country of Origin** China

This manufacturing lot has met CELLTREAT quality standards and has been accepted by quality assurance.

Product Quality Department  
CELLTREAT Scientific Products, LLC

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