

## **Certificate of Quality**



## **VWR® DISPOSABLE SEROLOGICAL PIPETS**

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	89130-898
EU Article No:	NA
Lot Number:	07918006
Description:	VWR PIPETTE SERO 10ML PR CS200
Manufacturing Date:	03/20/2018
Expiration Date:	03/19/2021

## **Component Materials:**

Pipette Polystyrene, meets USP Cytotoxicity Test <87>.
Mouthpiece Plug Polyester, meets USP Cytotoxicity Test <87>.

Ink meets USP Cytotoxicity Test <87>.

## **Volumetric Accuracy:**

This product has been tested and is accurate within +/- 2% at stated full volume.

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	<u>Results</u>
Visual Attributes	Pass
Volumetric Accuracy	Pass
Packaging	Pass

**Sterilization:** The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 "Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization".

Sterility Assurance Level: SAL 10-3

**Pyrogens:** The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing". **Results:** </= 0.1 EU/mL (</= 4 EU/device)

**DNase/RNase:** The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing". **Results:** </= 0.1 EU/mL (</= 4 EU/device)

**Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:** This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

Signed:

Linda K. Shine

Manager - Supplier Qualification

Global Compliance

**VWR International LLC** 

Date: April 04, 2018