



## VWR<sup>®</sup> DISPOSABLE SEROLOGICAL PIPETS, POLYSTYRENE, STERILE, PLUGGED

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

North American Catalog No:	89130-896
Lot Number:	16018007
Description:	VWR PIPETTE SERO 5ML PR CS200
Manufacturing Date:	June 09, 2018
Expiration Date:	June 08, 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	<b>Results</b>
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<sup>-3</sup>

**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.

This document has been produced electronically and is valid without a signature.

## Signed on behalf of VWR International:

Michael J. Mascali, RPh, FASCP, ASQ CMQ – OE SVP Compliance VWR International LLC

Date: July 10, 2018