



VWR® DISPOSABLE SEROLOGICAL PIPETS

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

North American Catalog No:	89130-896
EU Article No:	NA
Lot Number:	08418015
Description:	VWR PIPETTE SERO 5ML PR CS200
Manufacturing Date:	03/25/2018
Expiration Date:	03/24/2021

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:

<u>Test/Procedure</u>	<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:** $\leq 0.1 \text{ EU/mL}$ ($\leq 4 \text{ EU/device}$)

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:** $\leq 0.1 \text{ EU/mL}$ ($\leq 4 \text{ EU/device}$)

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 18, 2018