



## **Quality Certificate**

## **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	01418001
Description	VWR PIPETTE SERO 10ML PR CS200
Manufacturing Date:	01/14/2018
Expiration Date:	01/13/2021

## **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 healthcare 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 Free:** 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:

Junda K. Shine

Linda K. Shine Manager - Supplier Qualification Global Compliance VWR International LLC

Date: February 01, 2018

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