



## **Quality Certificate**

## **VWR® DISPOSABLE SEROLOGICAL PIPETS**

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

North American Catalog No	89130-896
EU Article No:	612-4950
Lot Number	36217010
Description	VWR PIPETTE SERO 5ML PR CS200
Manufacturing Date:	12/28/2017
Expiration Date:	12/27/2020

## **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<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)

**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:

Jorda K. Shine

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

Date: January 17, 2018

VWR International LLC, Radnor Corporate Center, Building One, Suite 200, 100 Matsonford Road Radnor, PA 19087 VWR International byba/sprl, Haasrode Research Park Zone 2020, Geldenaaksebaan 464, 3001 Leuven, Belgium