



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: | NA |
| Lot Number | 07318011 |
| Description | VWR PIPETTE SERO 5ML PR CS200 |
| Manufacturing Date: | 03/14/2018 |
| Expiration Date: | 03/13/2021 |

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 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 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:

K Shine

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

Date: March 28, 2018

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