



VWR® DISPOSABLE SEROLOGICAL PIPETS, PREMIUM LINE

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

North American Catalog No:	76184-752
Manufacture Lot Number:	200426245
Description:	VWR Pipet Serological St Ps Pink 100ml
Date of Manufacture:	April 26, 2020
Date of Sterilization:	April 29, 2020
Expiration Date:	April 26, 2023
Country of Origin:	Made in China

Quality System Compliance

Products are manufactured under the ISO 9001:2015 & ISO13485:2016 standard. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

QC Testing

Representative production samples are collected and inspected in accordance with current applicable product specifications.

Testing parameters and their results:

<u>Test/Procedure</u>	<u>Results</u>
Visual Attributes	Pass
Volumetric	Pass
Gastight Test	Pass
Ink fastness	Pass
Packaging	Pass

Product Specifications

This product is Class I category device as defined by the FDA in 21CFR Parts 862-892.

Material- Pipet:	GPSS (General purpose Polystyrene, Compliance with USP Class VI; Colour: Clear)
Mouthpiece Plug:	Polyolefin
Volumetric Accuracy:	Volumetric Accuracy is calibrated for accurate dispensing to within $\pm 2\%$ of full range.
Sterilization:	Product labeled as sterile is EB (Electron Beam) and dose released upon ISO 11137 recommended practices in effect at the time of validation. Products labeled sterile meet a minimum requirement of 10^{-6} SAL with a specified dose range of 15–30 kGy
BSE/TSE Statement:	The above product contains no ingredients of animal origin and no material derived from, or exposed to animals affected by or under quarantine for Transmitting, Animal Spongiform Encephalopathy (TSE)/Bovine Spongiform Encephalopathy (BSE).
Non-Pyrogenic:	The acceptance level for product is 0.06 EU/ml (TAL Gel Clot Method). Test Passed.
DNase & RNase Free:	This product has been tested and is free of any detectable DNase/RNase contamination.
Cytotoxicity:	Testing is conducted to qualify all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
Latex-Free Statement:	The product is Latex free.



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Haemolytic statement :	These Serological Pipets had no effect on hemolytic properties under this test condition (HR less than 5% considered acceptable)
BPA Statement:	Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used in the manufacture or the formulation of the raw materials and are not expected to be present. However, tests have not been performed for these chemical materials.
DEHP Statement:	Diethylhexyl phthalate (DEHP) is not included in the manufacture or formulation of the raw materials and are not expected to be present. However, test have not been performed for these chemical materials.
Heavy metals – RoHS:	Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/Eu concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).
Storage Conditions:	Storage at normal temperature.
Food contact statement:	The composition of the product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

Signed:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 15, 2020