

Certificate of Quality

VWR Catalogue Number	See List
Description	VWR Serological Pipette, Sterile
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-08-20

VWR Catalogue Number	Volume
76320-276	5 mL

Quality System Compliance

Products are manufactured under the **ISO 9001: 2015 & ISO 13485: 2016** standard. Products are inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP.

QC Testing

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

Test/Procedure	Results
Visual Attributes	Pass
Volumetric	Pass
Ink fastness	Pass
Packaging	Pass

Volumetric Accuracy Volumetric Accuracy is calibrated for accurate dispensing to within $\pm 2\%$ of full range.

Haemolytic statement Product had no effect on haemolytic properties under this test condition (HR less than 5% considered acceptable).

Food contact statement Product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

Product Specifications

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

Material **Pipet and Mouthpiece Plug:** General purpose Polystyrene (GPPS)
Compliance with USP Class VI; Colour: Clear.

Sterilization	Product is Gamma irradiated and dose released upon ISO 11137 recommended practices in effect at the time of validation and they meet a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 12- 24 kGy.
ATP Assay	Not applicable.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE).
Cytotoxicity	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
Non-Pyrogenic Statement	The acceptance level for product is 0.06 EU/ml. (TAL Gel Clot Method).
Latex Statement	The product is Latex free.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Not Applicable.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr ⁶⁺), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed.
REACH Statement	Not applicable.
Storage Conditions	Store at room temperature.
Shelf Life	3 years.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
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