

Certificate of Quality

VWR Catalogue Number	See List
Description	VWR® Milk Testing Pipets, Sterile
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2022-02-07

VWR Catalogue Number	Capacity [mL]	Colour
76288-784	1.1	Purple
76288-786	1.1	Purple
76288-788	2.2	Black
76288-790	2.2	Black

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.

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

Food contact statement: The composition of the product complies with the requirements of the 21 CFR 177.1640 "Polystyrene and rubber modified polystyrene".

Test/Procedure	Results
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: General purpose Polystyrene (GPPS) Compliance with USP Class VI; Colour: Clear. Mouthpiece Plug: Polyolefin
Sterilization	Product is EB (Electron beam) irradiated, and dose released upon ISO11137 recommended practices in effect at the time of validation. Products meets a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 15-30 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 0.5 EU/ml or less than 20 EU/device. (TAL Gel Clot Method).
Latex Statement	The product is Latex free.
Haemolytic statement	These Serological Pipets had no effect on haemolytic properties under this test condition. (HR less than 5% considered acceptable)
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
APHA Statement	The product meets APHA requirements shown in Standard Methods for Examination of Dairy Products and ASTM E1043-00 (2010).
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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