

Certificate of Conformity

VWR Catalogue Number	See List
Description	Serological pipettes, Open end, Sterile
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-11-01

Catalogue Number	Capacity [mL]	Division [mL]	Colour Code	Packed
612-5855	1	0.1	Yellow	Individually wrapped (paper/plastic), 500 Packs
612-5856	1	0.1	Yellow	Bulk vacuum packed, 1000 Packs
612-5857	2	0.01	Green	Individually wrapped (paper/plastic), 500 Packs
612-5858	2	0.01	Green	Bulk vacuum packed, 1000 Packs
612-5859	5	0.1	Blue	Individually wrapped (paper/plastic), 400 Packs
612-5860	5	0.1	Blue	Bulk vacuum packed, 400 Packs
612-5861	10	0.1	Orange	Individually wrapped (paper/plastic), 400 Packs
612-5862	10	0.1	Orange	Bulk vacuum packed, 400 Packs

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 QC requirements.

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

Product Specifications

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

Material	Pipet : GPPS (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 labelled as sterile is EB (Electron beam) irradiated as per ISO 11137 and meets SAL 10^{-6} with a specified dose range of 15-30kGy.
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). Test passed.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Please see RoHS information below.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethylhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analysis is performed.

REACH Statement	Not Applicable.
Storage Conditions	Store 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".
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.
This document has been produced electronically and is valid without a signature.