Certificate of Conformity

VWR Catalogue Number	612-6769
Description	VWR® Pipette Tips,1000 µl, Super Low retention, DNase/RNase-free, Non-Pyrogenic, with Filter, Sterile
Lot Number	210411307B
Date of Manufacture (yyyy-mm-dd)	2021-04-11
Date of Sterilization (yyyy-mm-dd)	2021-04-13
Date of Expiry (yyyy-mm-dd)	2024-04-11
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-06-14

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.

Trace Metal: All materials are certified as metal-free.

PCR Inhibitor: Product is tested via PCR amplification and gel electrophoresis analyses. Samples must show normal amplification to be considered free of PCR Inhibitors.

Product Specifications

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

Material

Tips: Polypropylene (PP), Colour: Natural.
Rack: Polypropylene (PP). Colour: Grey/Blue.
Filter: Polyolefin (PO). Colour: White.

Sterilization	Product is EB (Electron Beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Product meets a minimum requirement of 10^{-6} SAL with a specified dose range of 15-30 kGy.
ATP Assay	This product has been tested and is ATP free.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
Nucleic Acid	This product has been tested and is free of any detectable Nucleic Acid.
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). Test passed.
Latex Statement	This product is not made from natural rubber latex.
BPA Statement	Bisphenol 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 (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), 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 in Room temperature.

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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