

Certificate of Conformity

VWR Catalogue Number	See List
Description	Disposable, Graduated Microcentrifuge tubes with Conical Bottom and attached cap
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-10-19

0.5 ml tubes

Catalogue Number	Colour	Sterility
525-1220	Natural	Non-Sterile
525-1246	Amber	Non-Sterile
525-1222	Assorted	Non-Sterile
525-1250	Blue	Non-Sterile
525-1251	Green	Non-Sterile
525-1248	Orange	Non-Sterile
525-1249	Purple	Non-Sterile
525-1221	Red	Non-Sterile
525-1247	Yellow	Non-Sterile

1.5 ml tubes

Catalogue Number	Colour	Sterility
525-1126	Natural	Non-Sterile
525-1178	Natural	Sterile
525-1223	Amber	Non-Sterile
525-1230	Assorted	Non-Sterile
525-1228	Blue	Non-Sterile
525-1229	Green	Non-Sterile
525-1225	Orange	Non-Sterile
525-1227	Purple	Non-Sterile
525-1226	Red	Non-Sterile
525-1224	Yellow	Non-Sterile

2.0 ml tubes

Catalogue Number	Colour	Sterility
525-1136	Natural	Non-Sterile
525-1127	Amber	Non-Sterile
525-1135	Assorted	Non-Sterile
525-1133	Blue	Non-Sterile
525-1134	Green	Non-Sterile
525-1129	Orange	Non-Sterile
525-1131	Purple	Non-Sterile
525-1130	Red	Non-Sterile
525-1128	Yellow	Non-Sterile

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.

Max. Relative Centrifuge force: Products labeled max relative centrifuge force has been validated on centrifuge force testing and the acceptance level for product with Conical-Bottom is 20,000×g.

Autoclave Test: This product has been tested at 121 °C for 20 min in a autoclave and it is of integrity, no distortion and no leak with cap after autoclave.

Low temperature test: This product has been tested at -80 °C for 24 hours in freezer and it is of integrity, no distortion and no leak with cap after freezing.

Product Specifications

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

Material Tube/Cap: Polypropylene (PP). Compliance with USP VI.

Sterilization	Product labeled as sterile is EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 15-30 kGy. (which is not applicable for Non-Sterile products).
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 0.05 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	Room Temperature.
Shelf Life	Product labelled as sterile has shelf life of 3 years which is not applicable for non-sterile products.

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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