

# Certificate of Quality

<b>VWR Catalogue Number</b>	See List
<b>Description</b>	VWR® Microcentrifuge Tubes with Socket Screw Cap
<b>Country of Origin</b>	Manufactured in China
<b>Date of Issue (yyyy-mm-dd)</b>	2020-11-26

Clear Tubes with green colour Screw caps in separate resealable bags

VWR Catalogue Number	Volume [mL]	Graduations	Sterility	Style
89004-280	0.5	No	Non - Sterile	Conical Bottom
89004-284	0.5	No	Non - Sterile	Freestanding
89004-288	1.5	Yes	Non - Sterile	Conical Bottom
89004-292	1.5	Yes	Non - Sterile	Freestanding
89004-296	2	Yes	Non - Sterile	Conical Bottom
89004-300	2	Yes	Non - Sterile	Freestanding

Clear Tubes with attached green colour Screw Caps

VWR Catalogue Number	Volume [mL]	Graduations	Sterility	Style
89004-282	0.5	No	Sterile	Conical Bottom
89004-286	0.5	No	Sterile	Freestanding
89004-290	1.5	Yes	Sterile	Conical Bottom
89004-294	1.5	Yes	Sterile	Freestanding
89004-298	2	Yes	Sterile	Conical Bottom
89004-302	2	Yes	Sterile	Freestanding

Clear Tubes with Natural colour loop style caps

VWR Catalogue Number	Volume [mL]	Graduations	Sterility	Style
89004-312	0.5	No	Non - Sterile	Conical Bottom
89004-316	0.5	No	Non - Sterile	Freestanding
89004-304	1.5	Yes	Non - Sterile	Conical Bottom
89004-320	1.5	Yes	Non - Sterile	Freestanding
89004-308	2	Yes	Non - Sterile	Freestanding
89004-324	2	Yes	Non - Sterile	Conical Bottom

### 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.

**Maximum Relative Centrifuge force:** Products has been validated on centrifuge force testing. The acceptance level for product is 20,000×g.

**Autoclave Test:** Products has been tested at 121 °C for 20 min in an autoclave and it is integer, no distortion, and no leak with cap after autoclave.

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

### Product Specifications

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

**Material**  
 Tube Polypropylene; Compliance with USP Class VI  
 Cap Polypropylene; Compliance with USP Class VI

**Sterilization**  
 Product labelled as sterile are EB (Electron Beam) irradiated and dose released upon ISO 11137 recommended practices in effect at the time of validation and they meet a minimum requirement of 10<sup>-6</sup> SAL with a specified dose range of 15 - 30 kGy.

**ATP Assay** Not applicable.

<b>DNase &amp; RNase Free</b>	This product is free of any detectable DNase/RNase contamination.
<b>BSE/TSE</b>	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).
<b>Cytotoxicity</b>	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
<b>Non-Pyrogenic Statement</b>	The acceptance level for product is 0.05 EU/ml. (TAL Gel Clot Method).
<b>Latex Statement</b>	The product is latex free.
<b>BPA Statement</b>	Bisphenol are not used in the manufacture of the raw material and are not expected to be present.
<b>DEHP Statement</b>	Not applicable.
<b>RoHS</b>	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr <sup>6+</sup> ), 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.
<b>REACH Statement</b>	Not applicable.
<b>Storage Conditions</b>	Store at room temperature.
<b>Shelf Life</b>	Products labelled as sterile has shelf life period 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.  
This document has been produced electronically and is valid without a signature.