

# Certificate of Quality

<b>VWR Catalogue Number</b>	See List
<b>Description</b>	VWR® Conical Bottom Centrifuge Tubes, Sterile
<b>Country of Origin</b>	Manufactured in China
<b>Date of Issue (yyyy-mm-dd)</b>	2021-06-17

VWR Catalogue Number	Volume [mL]	Fits	Max rcf [xg]
76234-748	225	Plug seal	7500
76234-744	250	Plug seal	7500
76234-746	500	Flat seal	7500

## 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.

**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

Cap High Density Polyethylene (HDPE)  
Bottle Polypropylene (PP); Complies with USP Class VI

### Sterilization

Products are EB (Electron beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products meet a minimum requirement of 10<sup>-6</sup> SAL with a specified dose range of 15-30 kGy.

<b>ATP Assay</b>	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 0.5 EU/mL or less than 20 EU/device. (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>	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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