

# Certificate of Quality

VWR Catalogue Number	See List
Description	VWR® Centrifuge Tubes with Conical-Bottom and Flat Cap, Standard Line
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-08-20

VWR Catalogue Number	Volume	Sterility
10026-080	15 mL	Non-sterile
10026-084	15 mL	Sterile
10026-082	15 mL	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 product specifications.

**Max. Relative Centrifuge force:** Products labeled max. relative centrifuge force has been validated on centrifuge force testing. The acceptance level for product is 3000×g.

## 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)  
**Tube** Polystyrene (PS)

**Sterilization**  
 Product labeled as sterile is EB (Electron beam) irradiated, and dose released upon ISO11137 recommended practices in effect at the time of validation. Product labeled as sterile meets a minimum requirement of 10<sup>-6</sup> SAL with a specified dose range of 15-30 kGy.

**ATP Assay** Not applicable.

**DNase & RNase Free** 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>	Bisphenols 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.