

## Certificate of Quality

VWR Catalogue Number	See List
Description	VWR® Light Sensitive Centrifuge Tubes with Conical Bottom, Blocks 100% UV lighting
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2021-06-02

VWR Catalogue Number	Volume [mL]	Max. rcf [g]	Cap Type	Sterility
10026-088	15	12,500	Plug	Sterile
10026-090	15	12,500	Plug	Sterile
10026-092	15	12,500	Plug	Non-Sterile
10026-094	50	12,500	Plug	Sterile
10025-682	50	12,500	Plug	Sterile
10025-684	50	12,500	Plug	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 product specifications.

Max. Relative Centrifuge force: Products has been validated on centrifuge force testing. The acceptance level for product with Conical bottom is 12,500×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 Cap High Density Polyethylene (HDPE)

Tube Polypropylene (PP)

Sterilization Product labelled as sterile is EB (Electron beam) irradiated and dose

released upon ISO11137 recommended practices in effect at the time of validation. Products labelled 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.

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 0.5 EU/ml or less than 20

EU/device. (TAL Gel Clot Method).

**Latex Statement** The product is Latex free.

**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 (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.

**REACH Statement** Not applicable.

**Storage Conditions** Store at room temperature.

Shelf Life 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.