

Certificate of Conformity

VWR Centrifuge Tube, 15 ml, Conical Bottom, Sterile

VWR International certifies that the specified products meet all VWR specifications and quality criteria for release. The products comply in every respect with the relevant particular specifications, drawings, relevant standards and regulations in force.

VWR International certifie que les produits mentionnés respectent toutes les spécifications et critères de qualité VWR. Les produits satisfont aux spécifications particulières, aux plans, aux normes et règlements en vigueur s'y rapportant.

VWR International bestätigt hiermit, daß die angegebenen Produkte alle VWR Spezifikationen und Qualitätskriterien zur Freigabe erfüllen. Die Produkte entsprechen in jeder Hinsicht den maßgeblichen Spezifikationen, den Zeichnungen sowie den relevanten Normen und gültigen Vorschriften.

VWR Catalog No: 525-0604

Lot No: 191214058

Date of Manufacture: 14th Dec 2019

Date of Sterilization: 17th Dec 2019

Expiry Date: 14th Dec 2022

Type	RCF max.	Capacity (ml)	Packed	Pk
Flat cap with integral sealing	12500 xg	15	50/bag, 10 bags/case	500

Material: Cap – High Density Polyethylene (HDPE)
Tube – Polypropylene (PP)

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

Quality System Compliance: Products are manufactured under the ISO 9001:2015 & ISO13485:2016 standard. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

QC Testing: Representative production samples are collected and inspected in accordance with current applicable product specifications.

Sterility: Products labeled as sterile is gamma irradiated and dose released upon ISO11137 recommended practices meets a minimum requirement of 10⁻⁶ SAL with the specified dose range of 12 - 24 kGy.

Certificate of Conformity

BSE/TSE Statement: The above product contains no ingredients of animal origin and no material derived from, or exposed to animals affected by or under quarantine for Transmitting, Animal Spongiform Encephalopathy (TSE)/ Bovine Spongiform Encephalopathy (BSE)

Non-pyrogenic: The acceptance level of product is less than 0.5 EU/ml or less than 20 EU/device by TAL Gel Clot Method.

DNase & RNase free: This product has been tested and is free of any detectable DNase/RNase contamination.

Cytotoxicity: Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Latex Free statement: Product is Latex Free

BPA Statement: Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used in the manufacture or the formulation of the raw materials and are not expected to be present. However, tests have not been performed for these chemical materials.

DEHP Statement: Not Applicable.

Heavy metals - RoHS: Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/Eu concerning the limits of cadmium, lead, mercury, hexavalent chromium, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).

Max. Relative Centrifuge force: Products labeled max. relative centrifuge force has been validated on centrifuge force testing. The acceptance level for product with conical-bottom is 12,500×g.

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

This document has been produced electronically and is valid without a signature

Date of Issue: **January 2020**