



VWR® MICROCENTRIFUGE TUBES WITH SOCKET SCREW-CAP

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	89004-286
Manufacture Lot Number:	200305281
Description:	VWR TUBE MICRO 0.5 SK ST PK500
Date of Manufacture:	March 05, 2020
Date of Sterilization:	March 21, 2020
Date of Expiration:	March 05, 2023
Country of Origin:	Made in China

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.

Product Specifications

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

Material:	Tube: PP (Polypropylene), Compliance with USP Class VI, Color:Natural. Cap: PP (Polypropylene), Compliance with USP Class VI, Color:Green.
Sterilization Procedure:	Product labelled as sterile is EB (Electron Beam) and dose released upon ISO11137 recommended practices at effect at the time of validation. Products labelled sterile meet a minimum requirement of 10 ⁻⁶ SAL with a specified dose range of 15-30 kGy.
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 for product is 0.05 EU/ml (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 qualify all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
Latex-Free Statement:	The 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.
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).
DEHP Statement:	Not applicable



Max. Relative Centrifuge force: Products labeled Max. Relative Centrifuge force has been validated on centrifuge force testing. The acceptance level for product with free-standing bottom is 20,000×g

Autoclave Test: This product has been tested at 121°C for 20 min in a 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.

Signed:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 15, 2020