

VWR® DISPOSABLE ASPIRATING PIPETS, POLYSTYRENE, STERILE

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

North American Catalog No:	414004-265
Manufacture Lot Number:	02162020
Description:	VWR Pipet Aspirating 2ml Cs200
Date of Manufacture:	February 16, 2020
Date of Sterilization	February 24, 2020
Expiration Date	February 16, 2024
Country of Origin:	Made in China

Quality System Compliance

Products are manufactured under the ISO 13485:2016 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 a Class I category device as defined by the FDA in 21CFR Parts 862-892.

Material:	100% High Clarity Polystyrene.
Sterilization Process:	Product labeled as sterile is gamma irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meet a minimum requirement of 10^{-6} SAL with a specified dose range of 22 – 40 kGy. Expiration date (Shelf life) is based on product and packaging shelf life, provided the product wrapper is not damaged.
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).
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:	N/A
Non-Pyrogenic:	The acceptance level for product is 0.5 EU/ml or less than 20 EU/device LAL Gel Clot Method. Test passed.
DNase & RNase Free:	This Product is DNase and RNase free
Cytotoxicity:	Testing is conducted to quality all material resins using ISO10993 standards for cytotoxicity and have been shown to be non-toxic.
Latex-Free Statement:	N/A

Signed:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 19, 2020