Certificate of Quality

VWR® NEXT GENERATION PIPET TIP REFILL SYSTEM

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

VWR Catalog Number	89201-528
European Article Number	732-1484
Lot Number	40822-951C4-951C
Description	VWR TIP 200UL AERO LTS PK960
Date of Manufacture	December 19, 2019
Date of Sterilization	January 02, 2020
Date of Expiration	2022-12
Country of Origin	Made in USA

Quality System Compliance

The product conforms to written material specifications and was manufactured under the manufacturer's registered and audited ISO 9001 quality system, and underwent lot testing as outlined in the manufacturer's laboratory procedures. These products come with the highest standard of quality assurance.

QC Testing

Each lot of item was produced in a tightly controlled environment and subjected to the manufacturer's rigorous testing and performance procedures. The products meet all stated standards for precision, clarity, warp, centrifugation and freedom from contamination.

Product Specifications

Material:

Pipet Tip Material: Polypropylene

Filter Material: Polyethylene

Certified free of Bisphenol A (BPA), phthalates and cytotoxic effects. Plastic resins used in product manufacturing have been tested for heavy metals using the prescribed USP method and confirmed to have levels lower than 1 ppm. Resins are USP Class-VI certified, RoHS, FDA regulation CFR 21, and are free of Substances of Very High Concern (SVHC), REACH compliant, and are FDA approved for food contact.

Non-Pyrogenic Statement:

Product samples are exposed to endotoxin-free water and the resulting extraction fluid is tested for contamination using the kinetic turbidimetric Limulus Amoebocyte Lysate (LAL) assay protocol and USP guidelines. All products tested must display less than 0.05 EU/ml to be certified free of endotoxin.

ATP Assay:

Product sample surfaces are tested for the presence of Adenosine triphosphate (ATP) using a controlled bioluminescence reaction to detect contamination. Luminescence data is compared to results generated by ATP-free surfaces and surfaces with known amounts of ATP as a positive control. The relative light units' result must indicate less than $2X10^{-12}$ mg/ul of ATP for the product to be certified as ATP free.

DNase & RNase Free:

Product samples are exposed to nuclease-free water and the resulting extraction fluid is tested for nuclease activity on commercially available 7.5 kb Poly(A) tailed RNA (1ug) and HindIII- digested DNA (1ug) with a one hour 37 °C incubation in appropriate buffers. Results are visualized on an agarose gel with appropriate positive and negative controls. Extraction fluid samples must show no degradation of the nucleic acids by the extraction fluid has occurred for the product to be certified as RNase-free and DNAse-free.

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BSE/TSE Statement:

(Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy)
The product contains resins that are processed under one of the following sets of conditions: Hydrogenation of Tallow at 200 ºC
Hydrolysis at 260 ºC and 48 bar for 1.5 to 2 hours Vacuum distillation a 232 ºC
or
Hydrolysis of Tallow at 260 ºC and 700 PSIG for 3 hours Hydrogenation of Steric Acid a 232 ºC and 300 PSIG for 2.5 hours Distilled at 232 ºC for 5 minutes.
These conditions exceed the European Union standard as listed in the 22nd Commission Directive EC 98/16/EC of March 5th, 1998 as annexed to council Directive EC 76/768/EEC and further Amendment 419 Annex II of 12 June 2001, and as agreed to by the Scientific Committee on Cosmetics Recommendations concerning Tallow derivatives for processing conditions of 200 ºC and 40 bars for 20 minutes.
The manufacturer does not store any products of animal origin, including animal proteins, in any manufacturing areas of their facility or warehouses.

DNA Contamination Assay:

Product samples are exposed to DNA-free water and the resulting extraction fluid is tested for the presence of human DNA using primers for known DNA sequences in a PCR reaction. Amplification products are examined by Agarose gel electrophoresis with appropriate positive and negative controls. PCR reactions using extraction fluid must show less PCR- amplified product compared to a positive control containing human genomic DNA for the product to be certified as DNA-free.

Protease Assay:

Product samples are exposed to protease-free water and the resulting extraction fluid is tested for the presence of protease activity by examining test protein degradation in the extraction fluid compared to a negative control and positive control reactions supplemented with Proteinase K or Trypsin. Extraction fluid samples must show no test protein degradation relative to the negative control for the product to be certified as protease- free.

Sterilization Process:

Products from the specified lot number was processed by e-beam radiation at a dose range of 15.2-32.0 kiloGray. This dosage is sufficient to guarantee a sterility assurance level of 10^{-6}. Sterility assurance levels are based on the probability of a positive, nonsterile part occurring after irradiation. An SAL of 10^{-6} is the highest level of sterility able to be guaranteed according to the ISO 11137 standard and represents a 1 in 1,000,000 chance of a nonsterile part occurring. The Manufacturer's sterilization program is an ISO 11137 validated process, with bioburden studies and radiation validation audits performed quarterly.

Specified Dosage Range:	15.20 - 32.00 kGy
Minimum Dosage Delivered:	16.6kGy
Maximum Dosage Delivered:	29.9kGy

Latex Statement:

No Latex was used in the manufacturing of the product. This also includes all the packaging and shipping materials used in the production of all items.
The only time the product or packaging may come in contact with Latex would be from the Latex gloves that production employees are required to wear for the purpose of clean handling and to avoid biological contamination of the products.

Disclaimer: *VWR states that this declaration will not discharge the user from his obligation to ensure the product is suitable for the intended use.*

This Certificate was automatically generated and is valid without a Signature.

Date: January 17, 2020