

# **Certificate of Quality**



### **VWR® NEXT GENERATION PIPET TIP REFILL SYSTEM**

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

VWR Catalog Number	89079-458
European Article Number	613-0732
Lot Number	952C4-952AL
Description	VWR TIP YEL 200UL REFILL PK960
Date of Manufacture	December 29, 2019
Date of Expiration	2023-12
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

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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<sup>-12</sup> mg/ul of ATP for the product

to be certified as ATP 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 °C

Hydrolysis at 260 °C and 48 bar for 1.5 to 2 hours

Vacuum distillation a 232 °C or

Hydrolysis of Tallow at 260 °C and 700 PSIG for 3 hours Hydrogenation of Steric Acid a 232 °C and 300 PSIG for 2.5 hours

Distilled at 232 °C 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 °C 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.

#### 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