# **Quality Certificate**



# 3201 1250µL Pipette Tips, Biolog, VistaRak, Sterile 960/CS, 192 Tips/Rack

Lot Number: 241001R Expiration Date: 10/01/2027

This product is assembled in accordance with ISO 9001:2015 quality management systems in a class 100,000 clean room.

#### **Component Materials**

Polypropylene: meets USP, Class VI requirements.

#### **Sterilization Assurance Level**

Pre-sterilization is by electron beam radiation with post-sterilization verification. This lot has been processed and tested in accordance with ISO 11137-2. Product samples are bio-burdened.

### Cytotoxicity

All material resins are qualified using USP and/or ISO 10993 standards for cytotoxicity and have been shown to be non toxic.

#### Non-pyrogenic

< 0.06 EU/mL This product has been tested and meets the USP and ANSI/AAMI ST72:2011 guidelines and FDA regulations of endotoxin limit for medical devices at 0.06 EU/mL.

#### **RNase/DNase Testing**

RNase < 10-9 Kunitz units/ $\mu$ L, DNase < 10-7 Kunitz units/ $\mu$ L This product has been tested and is free of any detectable RNase and DNase.

## **Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy**

Resins, inks and packaging materials are not of animal origin and do not contain, make use of, or involve, at any point in the manufacturing process, raw materials of animal origin, including animal proteins.

## **Quality Control Testing**

Representative Samples have been selected and inspected according to ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection for Attributes. This lot has passed inspection.

#### **Country of Origin**

USA

This manufacturing lot has met quality standards and has been accepted by quality assurance.