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**Date:** June 27, 2018

Catalog Number: 89130-898

**Lot Number:** 16318030

**Product Description:** PIPETTE,VWR,10ML,PPW,PS,S,IND,

Manufacturing Date: 6/12/2018 Expiration Date: 6/11/2021

**Component Materials:** 

Pipette - Polystyrene, meets USP Cytotoxicity Test <87>.

Mouthpiece Plug - Polyester, meets USP Cytotoxicity Test <87>.

Ink - meets USP Cytotoxicity Test <87>.

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

This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

#### Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 "Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization". Sterility Assurance Level: SAL 10<sup>3</sup>

### **Pyrogens:**

The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing". Results: </= 0.1 EU/mL (</= 4 EU/device)

### **DNase/RNase Free:**

The product has been tested and has met the criteria established in ANSI/AAMI ST 72:2002/(R) 2010: "Bacterial Endotoxins - Test methodologies, routine testing, and alternative to batch testing". Results: </= 0.1 EU/mL (</= 4 EU/device)

## **Volumetric Accuracy:**

This product has been tested and is accurate within +/- 2% at stated full volume.

This manufacturing lot has been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics:

Test/Procedure: Results:

Visual Attributes Pass

Volumetric Accuracy Pass

Packaging Pass

Jason Jens

Plant Quality Manager

Rev. No. 6