



## VWR® INOCULATING LOOPS AND NEEDLES, STERILE

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

<b>VWR Catalog Number:</b>	12000-810
<b>Lot Number:</b>	200428-268
<b>Description:</b>	VWR Loop Inoculatn 10µL CS1000
<b>Date of Expiration:</b>	April 28, 2023

### Quality System Compliance

Products are manufactured in accordance with ISO 13485:2016 & ISO 9001:2015 quality management systems in a class 100,000 clean room.

### QC Testing

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.

### Product Specifications

**Sterilization:** Product labeled as sterile is irradiated and dosimetrically released upon ISO11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. These products labeled sterile meet a minimum requirement of  $10^{-6}$  SAL (Sterility Assurance Level).

**Non-Pyrogenic:** Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and Company guidelines. The acceptance level for product is less than 0.5 EU/mL.

**DNase & RNase Free:** This product has been tested and is free of any detectable DNase / RNase contamination.

Signed:



Jamie Ethier  
VP Global Quality  
VWR, Part of Avantor

**Date:** October 15, 2020