



# Certificate of Calibration and Sterility

Calibrated Disposable Inoculating Loops 1  $\mu$ L  
Calibrated Disposable Inoculating Loops 10  $\mu$ L  
Disposable Inoculating Needles



## INTENDED USE

Calibrated Disposable Inoculating Loops are suitable for use in semi-quantitative inoculation procedures such as urine counts, sampling, serial dilution and bacteriological inoculation.

## CALIBRATION STANDARD

The delivery volume of each batch of Calibrated Disposable Inoculating Loops are tested per the Evans Blue Dye Colorimetric Procedure as described in the Clinical Microbiology Procedures Handbook (American Society for Microbiology, Washington, DC.).

## QUALITY CONTROL

During manufacture, in-process testing and strict Statistical Process Control assure that product maintains an inner dimensional accuracy of  $\pm 12,5\%$  for 1  $\mu$ L loops and  $\pm 5\%$  for 10  $\mu$ L loops. Post production testing of samples taken according to ANSI/ASQC standards assures that manufactured lots conform with dimensional accuracy specifications. (American National Standards Institute/American Society for Quality Control: Z1.9-1980 Sampling Procedures and Tables for Inspection by Variables and Z1.4-1993 Sampling Procedures and Tables for Inspection by Attributes). In actual use, several factors may affect the collecting and dispensing of bacterial specimens, including operator technique and, among others, the viscosity and surface tension of the specimen. It is recommended that the user verify calibration for each application and adjust for the variances present.

## STERILITY

This document also certifies that the product contained here within has been sterilized using validated methods. Additionally, this specific lot of product was exposed to the necessary dosage required to meet established sterilization specifications.

