

PRODUCT CODE and DESCRIPTION:

WR086-03-0601 Double Nichrome Loop 10µL

LOT #	MANUFACTURING DATE	QUANTITY
2400644-14	2025/04/04	182,00

Product Visual Appearance according to internal SOP: *passed*

Product dimension controls according to internal SOP: *passed*

All reported results were obtained at time of Lot release.

COPAN WASP S.r.l. certifies that product quality requirements have been met, information stated above is correct, and that the Manufacturer Quality Management System is compliant to the standards EN ISO 13485:2016 Medical devices - Quality management systems – Requirements for regulatory purposes and EN ISO 9001:2015 Quality Management System – Requirements and following amendments.

1µL/10 µL LOOP CALIBRATION STATEMENT

Calibrated 1µL/10µL Inoculating Loops are suitable for use in semi-quantitative inoculation procedures such as urine counts, sampling and bacteriological inoculation. The 1 µL/10µL loops have been calibrated according to the criteria specified and described in the Clinical Microbiology Procedures Handbook, American Society for Microbiology, Washington, DC. The internal dimensions of the loop comply with the tolerance limitations which in turn correspond to the volume of liquid delivered by the loop. The delivery volume of the Calibrated Inoculating Loops is validated according to the Evans Blue Dye Colorimetric Procedure determining acceptable tolerance as $\pm 20\%$.

PRECAUTIONS

In actual use, several factors may affect the collecting and dispensing of bacterial specimens, including presence of debris inside the loop and, among others, the viscosity and surface tension of the specimen. Loop calibration is guaranteed when first used. Repeated heating and cooling to sterilize the loop, as well as loop cleaning procedure may cause changes in the internal diameter and width of the loop over time. To ensure continued accuracy loops must be regularly retested using a 1µL Loop Ring Checking Tool, ref. WSPD086-1002 provided by COPAN, to check the internal diameter. To ensure continued accuracy loops must be regularly retested using a 10µL Loop Ring Checking Tool, ref. WSPD086-1009 provided by COPAN, to check the internal diameter. Carefully follow gauge instruction for use. The frequency of loop retest should be defined by the end user accordingly to the internal Good Laboratory Practices and considering the criticality of the specific loop application.

30 µL LOOP PERFORMANCE STATEMENT

The 30 µL loops have been tested according to the internal criteria. The internal dimensions of the loop comply with the tolerance limitations which in turn correspond to the volume of liquid delivered by the loop (at least 30 µL).

PRECAUTIONS

In actual use, several factors may affect the collecting and dispensing of bacterial specimens, including presence of debris inside the loop and, among others, the viscosity and surface tension of the specimen. The frequency of loop retest should be defined by the end user accordingly to the internal Good Laboratory Practices and considering the criticality of the specific loop application.

2025/04/04

Certificate Date of Issue
(yyyy/mm/dd)



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