

 S GR11.6 DOC 25 REV09 OF 02/05/2024	CERTIFICATE OF STERILITY AND QUALITY ASSURANCE	N° 24-CRT03737
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CODE	LOT N°	EXP. DATE
323C	241066800	15/01/2026

DEVICE DESCRIPTION:	UTM 2ML REGULAR FLOCKED APPLICATOR
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1. Appearance: The medium is clear and light rose-orange in color.
2. Manufacture date: 15/07/2024
3. pH of the medium at 25°C acceptability limits $7,3 \pm 0,2$: passed
4. USP Membrane Filtration Sterility Test: Passed
5. Culture Response:

Swabs were inoculated with the test organisms and placed in the UTM medium. Good recovery of all organisms was obtained after 48 hours at 2-6°C and 20-24°C.

Test Organisms

Herpes Simplex Virus Type 2	ATCC VR-734
Influenza A	ATCC VR-1679
Cytomegalovirus	ATCC VR-977
Coxsackievirus B1	ATCC VR-28
<i>Chlamydia trachomatis</i>	ATCC VR-880
<i>Mycoplasma pneumoniae</i>	ATCC 15531

All reported results were obtained following internal SOP instructions.

Goods has been manufactured according to the ISO 13485:2016 system.

By signing below, Copan Italia SpA certifies that the above quality requirements have been met and all information stated above is correct.

16/09/2024

Certificate Date of Issue



Quality Representative
Copan Italia SpA
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