

## CERTIFICATE OF STERILITY AND QUALITY ASSURANCE

N° 24-CRT02097

S GR11.6 DOC 25 REV09 OF 02/05/2024

CODE	LOT N°	EXP. DATE
359C	240673100	22/09/2025

DEVICE DESCRIPTION:	UTM MINI RT-1ML Medium For Virus, Chlamydia, Mycoplasma and	
	Ureaplasma Specimens Single Plastic Flocked swab Velvet Tipped	

1. Appearance: The medium is clear and light rose-orange in color.

2. Manufacture date: 22/03/2024

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
Influenza A
Cytomegalovirus
Coxsackievirus B1
Chlamydia trachomatis
Mycoplasma pneumoniae

ATCC VR-734
ATCC VR-1679
ATCC VR-977
ATCC VR-28
ATCC VR-28
ATCC VR-880
ATCC VS-880

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.

14/05/2024

Certificate Date of Issue

Quality Representative Copan Italia SpA

Julies Govere

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