

 S GR11.6 DOC 25 REV08 OF 21/03/2022	<b>CERTIFICATE OF STERILITY AND QUALITY ASSURANCE</b>	N° <b>23-CRT03091</b>
---	---	--------------------------

CODE	LOT N°	EXP. DATE
346C	230982800	26/12/2024

DEVICE DESCRIPTION:	UTM ROOM TEMP.3ML+PL.REG/FLOCK
---------------------	--------------------------------

1. Appearance: The medium is clear and light rose-orange in color.
2. Manufacture date: 26/06/2023
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 at the time of lot release.

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.

26/07/2023

Certificate Date of Issue



Quality Representative  
Copan Italia SpA

Via F.Perotti 10 – 25125, Brescia - Italy