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|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------|
| <br>S GR11.6 DOC 25<br>REV09 OF 02/05/2024 | <b>CERTIFICATE OF STERILITY AND QUALITY ASSURANCE</b> | N°<br><b>25-CRT03977</b> |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------|

| CODE | LOT N°    | EXP. DATE  |
|------|-----------|------------|
| 346C | 251149200 | 21/01/2027 |

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

1. Appearance: The medium is clear and light rose-orange in color.
2. Manufacture date: 21/07/2025
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.

30/07/2025

Certificate Date of Issue



Quality Representative  
Copan Italia SpA  
Via F.Perotti 10 – 25125, Brescia - Italy