

## CERTIFICATE OF ANALYSIS

**MODEL:** BioCapt® Single-Use Sampler (\*) **PRODUCT CODE:** 79001201 **BATCH:** 24A1802  
**MEDIA:** Tryptone Soya Agar  
**MANUFACTURING DATE:** 18 Jan 2024  
**EXPIRY DATE:** 18 Jan 2025  
**STORAGE CONDITIONS:** at 2-25°C until expiry date

(\*) BioCapt®: Registered trademark.

BioCapt Single Use: U.S. Patents 10,345,200 and 11,231,345.

[www.pmeasuring.com/trademarks-and-patents/](http://www.pmeasuring.com/trademarks-and-patents/)

### CHEMICAL/PHYSICAL TESTS

| TESTS                | SPECIFICATION                                                                                                                   | RESULT                                          |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Appearance           | Light amber coloured, clear to slightly opalescent gel forms in plates                                                          | Conforms                                        |
| pH specification     | 7.3±0.2                                                                                                                         | Conforms                                        |
| Filling media volume | 30ml±1ml                                                                                                                        | Conforms                                        |
| Media composition    | TSA (see technical data sheet)<br>Medium is prepared utilizing raw materials declared to be BSE-TSE<br>FREE by the manufacturer | Conforms                                        |
| Packaging            | Triple Wrapped Sterile Irradiated (T.W.S.I.)                                                                                    | Conforms                                        |
| Dose of irradiation  | ≥10 KGy                                                                                                                         | Conforms<br>Irradiation certificate Nr: 3501429 |

### STERILITY CONTROL (performed before gamma irradiation)

| TESTS                                                          | SPECIFICATION | RESULT   |
|----------------------------------------------------------------|---------------|----------|
| 32.5±2.5°C aerobic for 7 days<br>22.5±2.5°C aerobic for 7 days | No growth     | Conforms |

### FERTILITY – GROWTH PROMOTION TEST (performed after gamma irradiation)

| CONTROL STRAIN                | MEDIUM<br>INOCULATION LEVEL     | INCUBATION<br>CONDITIONS    | RECOVERY<br>SPECIFICATIONS | RECOVERY<br>RESULTS | RESULT   |
|-------------------------------|---------------------------------|-----------------------------|----------------------------|---------------------|----------|
| E. coli<br>ATCC 8739          | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 87.2%               | Conforms |
| P. aeruginosa<br>ATCC 9027    | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 103.6%              | Conforms |
| S. aureus<br>ATCC 6538        | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 83.6%               | Conforms |
| B. subtilis<br>ATCC 6633      | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 92.7%               | Conforms |
| C. albicans<br>ATCC 10231     | 10-100 viable<br>microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%                | 88.7%               | Conforms |
| A. brasiliensis<br>ATCC 16404 | 10-100 viable<br>microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%                | 94.2%               | Conforms |
| Environmental strain<br>#1    | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 82.9%               | Conforms |
| Environmental strain<br>#2    | 10-100 viable<br>microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%                | 91.3%               | Conforms |

**Growth Promotion Test** in accordance to harmonised EP – USP Pharmacopoeias chapter, by quantitative surface plating method.

**Recovery:** results as cfu enumeration on test batch agar plates x 100/cfu enumeration on reference tests.

**Reference medium for recovery tests:** Tryptone Soya Agar for all Bacteria and Sabouraud Dextrose Agar for Yeast & Mold species.

ATCC is registered trademark of American Type Culture Collection.

**DATE ANALYSIS START:** 18 Jan 2024

**BATCH STATUS:** Approved

**QUALITY CONTROL:** Cinzia Bovio

**QUALITY ASSURANCE:** Andrea Farronato

**DATE ANALYSIS END:** 23 Feb 2024

**DATE OF BATCH RELEASE:** 23 Feb 2024

**SIGNATURE:**



**SIGNATURE:**



## Certificate of Processing

STERIGENICS Via Marzabotto, 4 Minerbio BO 40061 Italy  
 TEL 39 051-6605998 FAX 39 051-6605574 [www.sterigenics.com](http://www.sterigenics.com)

R55480102

15-Feb-24 9:36:53 GMT

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**Customer Name:** ANICRIN SRL EUR IT SCORZE  
**P.O.#** 129

**Processing Facility:** Minerbio

**Work Order #** 3501429  
**Sales Order #** 3492504

10-25 kGy

CRIN GAMMA TREATMENT

**Irradiation Date/Time:**

14-Feb-24 11:24:58 GMT

| SO Line # | Qty      | UOM | Customer Item Number | Customer Item Description | Customer Lot Number | Customer Load Number |
|-----------|----------|-----|----------------------|---------------------------|---------------------|----------------------|
| 101.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402605       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 102.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402606       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 103.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402607       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 104.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402608       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 105.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402609       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 106.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402610       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 107.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402611       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
| 108.000   | 1        | PL  | 2821/24_984/24       | BioCapt Single Use        | WWW0004402612       | 129.2024             |
|           | Dose Map |     | 270_CRIN_984/24      | Std cycle 15 kGy          |                     |                      |
|           | 8        | PL  | <b>Total</b>         |                           |                     |                      |

### Quality Test Summary

| Op#    | Quality Test Description | Minimum Spec | Maximum Spec | Result   | Pass/Fail |
|--------|--------------------------|--------------|--------------|----------|-----------|
| 450.00 | Minimum Dose             | 10.0 kGy     | 25.0 kGy     | 14.2 KGY | Pass      |
| 450.00 | Maximum Dose             | 10.0 kGy     | 25.0 kGy     | 19.1 KGY | Pass      |

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: VALERIA LOSITO  
 Reason: Work Order Completions

Date: 15-Feb-24 09:36:13 GMT



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A.01 Mod.0

R.29 Mod.0

|                                         |                      |                           |                        |
|-----------------------------------------|----------------------|---------------------------|------------------------|
| Documento<br><b>DdT</b>                 | Numero<br><b>129</b> | Data<br><b>12/02/2024</b> | Pagina<br><b>1 / 1</b> |
| Partita IVA<br>IT 00500911201           | Codice Fiscale       |                           |                        |
| Causale Trasporto<br>Uscita in C/Lavoro | Modalità di consegna |                           |                        |
| Pagamento                               |                      |                           |                        |
| Banca d'Appoggio                        |                      |                           |                        |
| Banca                                   |                      |                           |                        |

Spett.le  
Sterigenics Italy Spa  
Via Marzabotto 4  
40061 Minerbio BO  
Italia

| Ref.     | Descrizione                                                                                       | UM     | Quantità |
|----------|---------------------------------------------------------------------------------------------------|--------|----------|
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A1701 Qtà: 3.312                   | BOX 46 | NR 3.312 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A1801 Qtà: 1.728                   | BOX 24 | NR 1.728 |
| 79001201 | BioCapt Single Use Tryptone Soy Agar box of 72 pcs<br>Lotto: 24A1802 Qtà: 1.656                   | BOX 23 | NR 1.656 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A1901 Qtà: 1.656 | BOX 23 | NR 1.656 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2001 Qtà: 1.584 | BOX 22 | NR 1.584 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2201 Qtà: 1.800 | BOX 25 | NR 1.800 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2202 Qtà: 1.656 | BOX 23 | NR 1.656 |
| 79001209 | BioCapt Single Use Tryptone Soy Agar with neutralizers box of 72 pcs<br>Lotto: 24A2302 Qtà: 1.656 | BOX 23 | NR 1.656 |
|          | confezione di contro campioni                                                                     |        | 2        |
|          | confezione piastre per analisi post irraggiamento                                                 |        | 3        |
|          | Contratto 2821/2024                                                                               |        |          |

|                                                                                                                                                                                                                                                                                                                         |            |                              |       |                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------------------------|-------|--------------------------------------|
| Note                                                                                                                                                                                                                                                                                                                    |            |                              |       |                                      |
| Contratto 2821/2024                                                                                                                                                                                                                                                                                                     |            |                              |       |                                      |
| Vettore<br>KIKO SPEED SRL<br>VIA TRIESTE 14<br>36061 BASSANO DEL GRAPPA VI<br>Partita IVA: IT 02967650249                                                                                                                                                                                                               | Peso Netto | Aspetto Esteriore dei Beni   |       | Trasporto a cura del                 |
|                                                                                                                                                                                                                                                                                                                         | Peso Lordo | Pallets<br>8                 | Colli | Inizio Trasporto<br>12/02/2024 12.00 |
| AVVISO IMPORTANTE: i Vs. dati anagrafici e la partita iva che appaiono sul presente documento saranno quelli che verranno utilizzati, salvo Vs. diversa precisazione, agli effetti dell' Art. 2 DPR 633/72.<br>Con questo avviso Ci consideriamo esonerati da qualsiasi responsabilità prevista dall'Art.41 DPR 633/72. |            | Firma Conducente (o Vettore) |       | Firma Destinatario                   |