

| Product | Batch | Manufacturing date | Expiration date |
|--|-----------|--------------------|-----------------|
| BioCapt Tryptic Soy Agar + Neutralizers Ref. 19102S (79001209) | 042817006 | 28.04.2017 | 2017.10.25 |

| Gamma Rays Treatment | Irradiation Dose (kGy) | Date |
|-----------------------------------|------------------------|------------|
| Treatment Certificate No. 198.835 | 12,5 | 03.06.2017 |

| Physical quality control | Specification | Results |
|--------------------------|---------------------|----------|
| Expected pH-value (25°C) | 7.3 ± 0.2 | 7.2 |
| Appearance of medium | Slightly opalescent | Conforms |
| Colour of medium | Light amber | Conforms |
| Filling media volume | 30 ml ± 1 ml | Conforms |
| Media Composition | BSE free | Conforms |

Sterility Control- Absence of contamination (before gamma irradiation)

| | |
|----------------------------------|----------|
| 32.5 ± 2.5 °C aerobic for 7 days | Conforms |
| 22.5 ± 2.5 °C aerobic for 7 days | Conforms |

Microbiological Performance- Growth Promotion Test (after gamma irradiation)

Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP
Reference media: Tryptic Soy Agar

Productivity, Method of control: Quantitative Inoculum: 10-100 CFU

| Control strains | Incubation | Expected Results | Recovery | Results |
|--|------------------------------------|-------------------------------|----------|----------|
| <i>Bacillus subtilis</i> ATCC® 6633 | Aerobic, 24-72 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |
| <i>Escherichia coli</i> ATCC® 8739 | Aerobic, 24-72 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |
| <i>Staphylococcus aureus</i> ATCC® 6538 | Aerobic, 24-72 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |
| <i>Pseudomonas aeruginosa</i> ATCC® 9027 | Aerobic, 24-72 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |
| <i>Candida albicans</i> ATCC® 10231 | Aerobic, 72- 120 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |
| <i>Aspergillus brasiliensis</i> ATCC® 16404 | Aerobic, 72- 120 h 32.5 ± 2.5°C | 70% ≤ P _R % ≤ 200% | 86 | Conforms |

RECOVERY: RESULTS AS CFU ENUMERAION ON TEST BATCH AGAR PLATES x 100/ CFU ENUMERATIONON REFERENCE TESTS.
REFERENCE MEDIUM FOR RECOVERY TESTS: TSA FOR ALL BACTERIA AND SDA FOR YEAST AND MOLD SPECIES
ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION

Batch Release

Approved

Date **07.06.2017**

Signature

Quality Control
(D. Vitagliano)



The results reported were obtained at the time of release.



ATTESTATO DI TRATTAMENTO Treatment Declaration

N° 198.835 **Data 05/06/2017**
No *Dated*

N° Rif. Lotto di Trattamento 5144/2017
Rif Batch No.

W.O. 1970144
S.O. 1704990

Mandante LIOFILCHEM S.R.L. (6)
Sender

Documento di trasporto N.° 6965
Delivery note No.

Del 30/05/2017
Dated

N° coll. 3
No of Batches

Ricevente LIOFILCHEM S.R.L. (6)
Consignee

Contratto Commerciale N° 2346/2015
Contract No.

Cliente LIOFILCHEM S.R.L. (6)
Customer

Codice Packing-List www_6_52680
Packing-List code

Descrizione Prodotto (Come indicato nel form della Packing-List elettronica inviata dal Cliente)
Description of goods (As declared in the digital Packing-List sent by the Customer)

042817006-050517078

Si dichiara che la merce sopra descritta è stata sottoposta a trattamento mediante esposizione a raggi gamma generati da Cobalto-60 utilizzando impianti e procedure di controllo conformi alle norme UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

We hereby declare that the above-mentioned goods have been irradiated with Cobalt-60 gamma rays using machinery and control procedures validated in accordance with UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

Sterigenics Italy si esime dalla responsabilità di eventuali errori di quanto indicato dal Cliente nella Packing-List elettronica
Sterigenics Italy will not be held responsible for any mistake in what indicated by the Customer in the digital Packing-List

Il processo di trattamento è stato effettuato secondo le specifiche del Capitolato di Fornitura: N°: 681/14 del 29/07/14
Treatment process has made in compliance with the specifications of the Supply Agreement: No. dated

Ciclo standard: 12,5 kGy
Standard Cycle

Dosimetro tipo Red Perspex 4034 Lotto: NW
Dosimeter Batch

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Soggetta a Direzione e Coordinamento di Deross Holding B.V.

