

Product	Batch	Manufacturing date	Expiration date
BioCapt Tryptic Soy Agar + Neutralizers Ref. 19102S (79001209)	100418111	2018/10/04	2019/10/04

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 214.267	12,5	2018.11.08

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 <sub>R</sub> % ≤ 200%	80%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	100%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	85%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	96%	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	75%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	104%	Conforms

RECOVERY: RESULTS AS CFU ENUMERATION ON TEST BATCH AGAR PLATES x 100/ CFU ENUMERATION ON 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	14.11.2018	Signature	Quality Control (D. Vitagliano)
The results reported were obtained at the time of release.			<i>Dario Vitagliano</i>

# ATTESTATO DI TRATTAMENTO

## Treatment Declaration

N° 214.267  
No

Data 08/11/2018  
Dated

N° Rif. Lotto di Trattamento 9542/2018  
Rif Batch No.

W.O. 2319675  
S.O. 2093867

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

Documento di trasporto N.° 15695  
Delivery note No.

Del 30/10/2018  
Dated

N° colli 7  
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\_62616  
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)*

101518065-080718009-090418029-10178079-090518146-10 0518055-100418111-100518043

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**  
*Treatment process has made in compliance with the specifications of the Supply Agreement:*

No. del 29/07/14  
dated

**Ciclo standard: 12,5 kGy**  
*Standard Cycle*

**Dosimetro tipo Red Perspex 4034 Lotto: PJ**  
*Dosimeter Batch*

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