

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers + Pyruvate</b>	050517078	05.05.2017	2017.11.01
<b>Ref. 19103S (79001206)</b>			

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 198.835	12,5	05.06.2017

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	7.3
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%	86	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	95	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	102	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	98	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	76	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 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)

*Dario 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° colli 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 nelle 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.

