

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers</b> Ref. 19102S (79001209)	060117024	01.06.2017	2018.02.26

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. <b>199.553</b>	<b>12,5</b>	<b>26.06.2017</b>

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	<b>7.2</b>
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%	75	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	88	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%	99	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	86	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	89	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 **29.06.2017**

Signature

Quality Control  
(D. Vitagliano)

*Dario Vitagliano*

The results reported were obtained at the time of release.

## ATTESTATO DI TRATTAMENTO Treatment Declaration

N° 199.553      Data 26/06/2017  
No                      Dated

N° Rif. Lotto di Trattamento 5880/2017  
Rif Batch No.                      W.O. 1986141  
S.O. 1718576

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

Documento di trasporto N.° 8022  
Delivery note No.

Del 21/06/2017  
Dated

N° colli 1  
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\_53194  
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)

060117024

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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Soc. Uninominale - Capitale Sociale € 2.500.000,00 i.v. - P.Iva IT00500911201  
C.F. e Reg. Imprese di Bologna 00307110379 - R.E.A. Bologna 194057  
Soggetta a Direzione e Coordinamento di Deross Holding B.V.

