

Product	Batch	Manufacturing date	Expiration date
BioCapt Tryptic Soy Agar	032218179	2018/03/22	2019/03/22

Ref. 19101S (79001201)

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 208.458	12,5	2018/05/09

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%	100%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	96%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	78%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	85%	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	101%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P _R % ≤ 200%	90%	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	2018/05/16	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° 208.458
No

Data 09/05/2018
Dated

N° Rif. Lotto di Trattamento 3611/2018
Rif Batch No.

W.O. 2199729
S.O. 1950563

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

Documento di trasporto N.° 5817
Delivery note No.

Del 18/04/2018
Dated

N° colli 2
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_59360
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)

032318029-032218179

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:PJ
Dosimeter Batch

Sterigenics Italy S.p.A - Via Marzabotto, 4 - 40061 MINERBIO (Bologna - Italia) Tel.
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Soc. Uninominale - Capitale Sociale € 2.500.000,00 I.v. - P.Iva IT00500911201
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Soggetta a Direzione e Coordinamento di Deross Holding B.V.

