

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Sabouraud Dextrose Agar + Neutralizers</b>	100417015	2017.10.04	2018.07.01
<b>Ref. 19107S (79001409)</b>			

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. <b>203.250</b>	<b>12,5</b>	<b>2017.10.30</b>

Physical quality control	Specification	Results
Expected pH-value (25°C)	5,6 ± 0.2	5.6
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

<b>Sterility Control- Absence of contamination (before gamma irradiation)</b>		
32.5 ± 2.5 °C aerobic for 7 days		Conforms
22.5 ± 2.5 °C aerobic for 7 days		Conforms

<b>Microbiological Performance- Growth Promotion Test (after gamma irradiation)</b>		
Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP		
Reference media: Sabouraud Dextrose Agar		

<b>Productivity, Method of control: Quantitative</b>				
Inoculum: 10-100 CFU				
Control strains	Incubation	Expected Results	Recovery	Results
<i>Candida albicans</i> ATCC® 10231	Aerobic, 48- 120 h 22.5 ± 2.5°C	70% ≤ P <sub>R</sub> ≤ 200%	98%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 48- 120 h 22.5 ± 2.5°C	70% ≤ P <sub>R</sub> ≤ 200%	101%	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 REGISTEREDTRADE MARK OF AMERICAN TYPE CULTURE COLLECTION

<b>Batch Release</b>			
Approved			
<b>Date</b>	2017.11.02	<b>Signature</b>	Quality Control (D. Vitagliano)
The results reported were obtained at the time of release.			<i>Dario Vitagliano</i>

## ATTESTATO DI TRATTAMENTO Treatment Declaration

N° 203.250  
No

Data 30/10/2017  
Dated

N° Rif. Lotto di Trattamento 9647/2017  
Rif Batch No.

W.O. 2072245

S.O. 1807429

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

Documento di trasporto N.° 13763  
Delivery note No.

Del 24/10/2017  
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\_55800  
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)

100417015

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. Uninomiale - 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.

