

Certificate of Conformance, Analysis, and Sterility

This certification is provided as full assurance that the following product code and lot number were manufactured in accordance via a Quality System certified to ISO 9001 with prescribed procedures and specifications.

Product Code:	PS-911EB/ETOH			
Lot Number:	1113283-0-0-1			
Manufacturing Date:	01/31/2025			
Ethyl Alcohol(denatured):	70 \pm 3% by volume with the remainder DI H2O.			
Expiration Date:	01/2027			
Analysis				
Quantity of Particles Po:1.772 millions/m²				
Sterility				
Gamma Processing Run ID:	3701903			
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy			
Irradiation Dose Delivered:	19.0 kGy to 34.9 kGy			
Validated Sterile Product:	Validation Sterile packets available upon request.			
Sterility Assurance Level:	10-6 (SAL determined by test method AAMI/ISO 11137)			

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QC Supervisor coc@contecinc.com

Thursday, February 13, 2025 NORTH AMERICA Contec, Inc. 525 Locust Grove Spartanburg, SC 29303 USA

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Certificate of Processing

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R55480102

R55480102						02/12/2025 17:43:0. Page 1 of 1	5 GMT
Customer Name: P.O.#		Contec- PO Box 530 147274		Processing Facility:	Charlotte Gamma	Work Order # Sales Order #	3701903 3734344
	18.2-40.0	kGy		CNT4, Gamma Treatment	Irradiation Date/Time:	02/11/2025 13:32:0	O GMT
SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number	
101.000	512 512	CA CA	PS-911EB/ETOH Total	Clean Room Product	1113283-0-0-1	147274	

Quality Test Summary

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Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	 Date /Time	
450.00	Minimum Dose	18.2 kGy	40.0 kGy	19.0 KGY	Pass	TDIAZ	02/12/2025 03:25:14 GMT	
		Reason Code Test				Faustino (Tino) Diaz		
450.00	Maximum Dose	18.2 kGy	40.0 kGy	34.9 KGY	Pass	TDIAZ	02/12/2025 03:25:36 GMT	
		Reason Code Test				Faustino (Tino) Diaz		

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: WENDY KOBLISH Reason: Work Order Completions

Date: 02/12/2025 17:33:36 GMT