

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: PSPS0093

Lot Number: 799106-0-0-1

Manufacturing Date: 08/26/2020

Expiration Date: 08/2022

Analysis

% v/v Isopropyl Alcohol: 71.493

Quantity of Particles Po: 3.3 millions/m²

Quantity of Fibers Po: 0.358 thousands/m²

Nonvolatile residue in DI: 0.00 g/m²

Nonvolatile residue in IPA: 0.0203 g/m²

Sterility

Gamma Processing Run ID: 2731853

Irradiation Dose Specified: 25 kGy to 50 kGy

Irradiation Dose Delivered: 28.5 kGy to 41.5 kGy

Validated Sterile Product: Validation Sterile packets available upon request.

Sterility Assurance Level: 10-6 (SAL determined by test method AAMI/ISO 11137)

QC Supervisor

coc@contecinc.com

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Certificate of Processing

STERIGENICS 10811 Withers Cove Park Dr. Charlotte NC 28278 TEL 704 588-6877 FAX 704 588-8355 www.sterigenics.com

R55480102

09/08/2020 12:25:39 GMT

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Customer Name: P.O.#

Contec- PO Box 530

112064

Processing Facility:

Charlotte Gamma

Work Order # Sales Order # 2731853 2581588

25-50 kGy

CNT6, Gamma Treatment

Irradiation Date/Time:

09/05/2020 04:48:00 GMT

SO Line #	Qty	MOU	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number	
101,000	72	CA	89108-160	16 oz IPA Spray Bottle 70/30	786714-0-0-1	112064	
102.000	72	CA	89108-160	16 oz IPA Spray Bottle 70/30	786715-0-0-1	112064	
103.000	72	CA	PSPS0093	Clean Room Product	799106-0-0-1	112064	
	216	CA	Total				

Quality Test Summary

						Signed By	-
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	50.0 kGy	28.5 KGY	Pass	SJDAVIS	09/06/2020 16:01:16 GMT
		Reason Code Test				STEVEN DAVIS	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	41.5 KGY	Pass	DHOWELL	09/05/2020 13:00:31 GMT
		Reason Code Test				DEREK HOWELL	

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: 09/08/2020 12:02:20 GMT