

## 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: **PSPS0076** 

Lot Number: 696327-0-0-1

Manufacturing Date: 04/06/2019

**Expiration Date:** 04/2021

**Analysis** 

% v/v Isopropyl Alcohol: 70.46

5.6 millions/m<sup>2</sup> Quantity of Particles Po:

Quantity of Fibers Po: 0.25 thousands/m<sup>2</sup>

Nonvolatile residue in DI:  $0.00 \text{ g/m}^2$ 

Nonvolatile residue in IPA: 0.0205 g/m<sup>2</sup>

**Sterility** 

Gamma Processing Run ID: 2417862

Irradiation Dose Specified: 25 kGy to 50 kGy

Irradiation Dose Delivered: 29.1 kGy to 45.3 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

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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

04/15/2019 12:22:26 GMT

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Customer Name: P.O.#

Contec- PO Box 530

99570

Processing Facility:

Charlotte Gamma

Work Order # Sales Order #

2417862 2210263

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

04/13/2019 07:37:00 GMT

SO Line #	Qty	MOU	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number	
101.000	54	CA	PSPS0076	Clean Room Product	696327-0-0-1	99570	
102.000	54	CA	PSPS0076	Clean Room Product	696328-0-0-1	99570	
103.000	54	CA	PSPS0076	Clean Room Product	696330-0-0-1	99570	
104.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	688950-0-0-1	99570	
	270	CA	Total				

## **Quality Test Summary**

			addity root daminary			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	29.1 KGY	Pass	MFREIBERG	04/13/2019 21:15:01 GMT
		Reason Code Test				MICHAEL FREIBERG	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	45.3 KGY	Pass	BPOSTON	04/13/2019 19:36:37 GMT
		Reason Code Test				BRANTT POSTON	

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: 04/15/2019 12:19:59 GMT