



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:	731929-0-0-1
Manufacturing Date:	10/28/2019
Expiration Date:	10/2021

Analysis

% v/v Isopropyl Alcohol:	70.135
Quantity of Particles Po:	2.88 millions/m ²
Quantity of Fibers Po:	0.061 thousands/m ²
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²

Sterility

Gamma Processing Run ID:	2548092
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	30.0 kGy to 43.1 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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Wednesday, November 13, 2019

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Certificate of Processing

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11/11/2019 14:20:35 GMT
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Customer Name: Contec- PO Box 530	Processing Facility: Charlotte Gamma	Work Order # 2548092
P.O.# 104479		Sales Order # 2360779
25-50 kGy	CNT1, Gamma Treatment	Irradiation Date/Time: 11/09/2019 05:04:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	54	CA	PSPS0076	Clean Room Product	731929-0-0-1	104479
102.000	36	CA	PSQS0001	Gamma Wipes	736362-0-0-1	104479
	90	CA	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Minimum Dose	25.0 kGy	50.0 kGy	30.0 KGY	Pass	FGDIAZ	11/09/2019 13:48:41 GMT
		Reason Code Test				FAUSTINO G. DIAZ	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	43.1 KGY	Pass	FGDIAZ	11/09/2019 13:48:53 GMT
		Reason Code Test				FAUSTINO G. 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: 11/11/2019 14:02:56 GMT