



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:	PSC20001-BPR
Lot Number:	885873-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	10/05/2021
Expiration Date:	10/2023

Analysis

% v/v Isopropyl Alcohol:	70.039
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Sterility

Gamma Processing Run ID:	2981376
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	30.8 kGy to 42.3 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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Wednesday, October 13, 2021

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Page 1 of 1

DID: 20605A



Certificate of Processing

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10/11/2021 13:09:30 GMT
Page 1 of 1

Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2981376
P.O.#	121087			Sales Order #	2885188
25-50 kGy		CNT1, Gamma Treatment	Irradiation Date/Time:	10/10/2021 00:28:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	54	CA	PSPS0076-BPR	Clean Room Product	889133-0-0-1	121087
102.000	84	CA	PSC20001-BPR	Clean Room Product	885873-0-0-1	121087
	138	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	30.8 KGY	Pass	DHOWELL	10/10/2021 10:04:00 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	42.3 KGY	Pass	DHOWELL	10/10/2021 10:04:20 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: BRITTANY LONG
Reason: Work Order Completions

Date: 10/11/2021 13:08:15 GMT