



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:	PSPP0039-BPR
Lot Number:	1124303-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	03/03/2025
Expiration Date:	03/2027

Analysis

Quantity of Particles Po:	0.64 millions/m ²
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Sterility

Gamma Processing Run ID:	3721853
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.2 kGy to 40.0 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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Thursday, March 13, 2025

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Certificate of Processing

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Customer Name: Contec- PO Box 530 Processing Facility: Charlotte Gamma Work Order # 3721853
P.O.# 148160 Sales Order # 3757672

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

03/08/2025 20:36:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	30	CA	PSPS0077	Clean Room Product	1127689-0-0-1	148160
102.000	36	CA	PSQS0001	Gamma Wipes	1126703-0-0-1	148160
103.000	36	CA	PSQS0001	Gamma Wipes	1128310-0-0-1	148160
104.000	36	CA	PSQS0001	Gamma Wipes	1128311-0-0-1	148160
105.000	72	CA	PSWE0003-BPR	PROSAT* PET 12X12 HF 70/30 IPA	1127033-0-0-1	148160
106.000	360	CA	PSPP0039-BPR	Clean Room Product	1124303-0-0-1	148160
107.000	72	CA	PSWE0002	Clean Room Products	1129781-0-0-1	148160
	642	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	27.2 KGY	Pass	DHOWELL	03/09/2025 09:40:04 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	40.0 KGY	Pass	DHOWELL	03/09/2025 09:40:17 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: 03/10/2025 15:25:14 GMT