



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:	PSPS0091-BPR
Lot Number:	1110057-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	12/17/2024
Expiration Date:	12/2026

Analysis

Quantity of Particles Po:	0.8 millions/m ²
Quantity of Fibers Po:	0.09 thousands/m ²
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.0203 g/m ²

Sterility

Gamma Processing Run ID:	3683139
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	25.8 kGy to 37.2 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, January 08, 2025

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DID: 20633A



Certificate of Processing

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01/06/2025 15:07:11 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3683139
P.O.#	146383			Sales Order #	3711495
25-50 kGy		CNT7, Gamma Treatment	Irradiation Date/Time:	01/05/2025 21:38:37 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	36	CA	PSPS0091-BPR	Clean Room Product	1110057-0-0-1	146383
	36	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	25.8 KGY	Pass	GDIAZ	01/06/2025 08:32:30 GMT
		Reason Code Test				FAUSTINO GERMAN DIAZ	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	37.2 KGY	Pass	GDIAZ	01/06/2025 08:32:46 GMT
		Reason Code Test				FAUSTINO GERMAN 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: BRITTANY LONG
Reason: Work Order Completions

Date: 01/06/2025 15:06:04 GMT