

Certificate of Conformance 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:	PSME0001-BPR
Lot Number:	1123243-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/10/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	02/2027

Sterility

Gamma Processing Run ID:	3710814
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.8 kGy to 38.7 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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Friday, February 28, 2025

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Certificate of Processing

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02/24/2025 15:21:38 GMT

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Customer Name: Contec- PO Box 530
P.O.# 147673

Processing Facility: Charlotte Gamma

Work Order # 3710814
Sales Order # 3744284

25-50 kGy

CNT6, Gamma Treatment

Irradiation Date/Time: 02/22/2025 22:33:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	60	CA	PSME0001	Clean Room Product	1121795-0-0-1	147673
102.000	60	CA	PSME0001	Clean Room Product	1121796-0-0-1	147673
103.000	60	CA	PSME0001	Clean Room Product	1121797-0-0-1	147673
104.000	60	CA	PSME0001	Clean Room Product	1121799-0-0-1	147673
105.000	72	CA	PSCS0009	Clean Room Product	1120936-0-0-1	147673
106.000	60	CA	PSME0001-BPR	Clean Room Product	1123242-0-0-1	147673
107.000	60	CA	PSME0001-BPR	Clean Room Product	1123243-0-0-1	147673
108.000	60	CA	PSME0001-BPR	Clean Room Product	1123244-0-0-1	147673
109.000	216	CA	HCFT7030IR	16 oz Sterile IPA w/ Flip Top	1107275-0-0-1	147673
110.000	216	CA	HCFT7030IR	16 oz Sterile IPA w/ Flip Top	1107276-0-0-1	147673
	924	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	27.8 KGY	Pass	DHOWELL	02/23/2025 08:18:58 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	38.7 KGY	Pass	DHOWELL	02/23/2025 08:19:10 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: 02/24/2025 15:05:05 GMT