



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
Lot Number:	1090597-0-0-1
Manufacturing Date:	09/12/2024
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	09/2026

Sterility

Gamma Processing Run ID:	3626595
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	30.2 kGy to 41.3 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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Monday, September 30, 2024

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Page 1 of 1

DID: 8621B



Certificate of Processing

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09/23/2024 13:58:48 GMT
Page 1 of 1

Customer Name: Contec- PO Box 530
P.O.# 144185

Processing Facility:

Charlotte Gamma

Work Order # 3626595
Sales Order # 3642238

25-50 kGy

CNT6, Gamma Treatment

Irradiation Date/Time:

09/21/2024 10:04:00 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	1090393-0-0-1	144185
102.000	60	CA	PSME0001	Clean Room Product	1090595-0-0-1	144185
103.000	60	CA	PSME0001	Clean Room Product	1090596-0-0-1	144185
104.000	60	CA	PSME0001	Clean Room Product	1090597-0-0-1	144185
	240	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	30.2 KGY	Pass	TDIAZ	09/21/2024 18:23:47 GMT
		Reason Code Test				Faustino (Tino) Diaz	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	41.3 KGY	Pass	TDIAZ	09/21/2024 18:24:09 GMT
		Reason Code Test				Faustino (Tino) 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: 09/23/2024 13:57:51 GMT