



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:	1087230-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	09/20/2024
Expiration Date:	09/2026

Analysis

% v/v Isopropyl Alcohol:	70.19
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Sterility

Gamma Processing Run ID:	3629899
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	29.2 kGy to 42.7 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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Monday, October 07, 2024

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DID: 20605A



Certificate of Processing

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09/30/2024 14:01:31 GMT
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Customer Name: Contec- PO Box 530
P.O.# 144364

Processing Facility:

Charlotte Gamma

Work Order # 3629899
Sales Order # 3646269

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

09/28/2024 08:55:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	72	CA	PSWE0001-BPR	Clean Room Products	1090075-0-0-1	144364
102.000	108	CA	89499-420	STERILE 70% IPA/ 30% DI 32 OZ	1091480-0-0-1	144364
103.000	108	CA	89499-420	STERILE 70% IPA/ 30% DI 32 OZ	1091481-0-0-1	144364
104.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1085294-0-0-1	144364
105.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1085295-0-0-1	144364
106.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1085296-0-0-1	144364
107.000	224	CA	PSC20001-BPR	Clean Room Product	1087230-0-0-1	144364
108.000	54	CA	PSPS0076	Clean Room Product	1092930-0-0-1	144364
	890	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	29.2 KGY	Pass	BTOWERY Benjamin Towery	09/28/2024 21:59:29 GMT
450.00	Maximum Dose	25.0 kGy	50.0 kGy	42.7 KGY	Pass	BTOWERY Benjamin Towery	09/28/2024 21:59:54 GMT

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: 09/30/2024 13:35:03 GMT