



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:	1099144-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	11/05/2024
Expiration Date:	11/2026

Analysis

% v/v Isopropyl Alcohol:	70.088
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Sterility

Gamma Processing Run ID:	3656128
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.4 kGy to 40.4 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, November 15, 2024

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DID: 20605A



Certificate of Processing

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Customer Name: Contec- PO Box 530
P.O.# 145345

Processing Facility:

Charlotte Gamma

Work Order # 3656128
Sales Order # 3678169

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

11/09/2024 08:42:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	108	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1091530-0-0-1	145345
102.000	552	CA	76490	Clean Room Product	1098319-0-0-1	145345
103.000	150	CA	PSC20001-BPR	Clean Room Product	1099144-0-0-1	145345
104.000	54	CA	PSPS0076	Clean Room Product	1097782-0-0-1	145345
	864	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 Reason Code Test	50.0 kGy	27.4 KGY	Pass	MPAPADIM MANOLIS PAPADIMITRIOU	11/09/2024 23:11:53 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	50.0 kGy	40.4 KGY	Pass	MPAPADIM MANOLIS PAPADIMITRIOU	11/09/2024 23:12:22 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: BRITTANY LONG
Reason: Work Order Completions

Date: 11/11/2024 15:38:51 GMT