

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:	1130718-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	03/06/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	03/2027

Sterility

Gamma Processing Run ID:	3727110
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	28.0 kGy to 37.7 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
coc@contecinc.com

Tuesday, March 25, 2025

NORTH AMERICA

Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA
tel: +1 864 503 8333
fax: +1 864 503 8444

EUROPE

Contec Europe
ZI Du Prat, Avenue Paul Dupleix
56000 VANNES France
tel: +33 (0)2 97 43 76 98
fax: +33 (0) 97 43 76 86

ASIA

Contec Cleanroom Technology (Suzhou) Co., Ltd.
17 Longyun Road
Suzhou Industrial Park, Suzhou 215024 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

web: www.contecinc.com
e-mail: info@contecinc.com



Certificate of Processing

STERIGENICS 10811 Withers Cove Park Dr. Charlotte NC 28278
 TEL 704 588-6877 FAX 704 588-8355 www.sterigenics.com

R55480102

03/24/2025 15:13:49 GMT
 Page 1 of 1

Customer Name: Contec- PO Box 530
 P.O.# 148351

Processing Facility:

Charlotte Gamma

Work Order # 3727110
 Sales Order # 3763788

25-50 kGy

CNT6, Gamma Treatment

Irradiation Date/Time:

03/22/2025 06:00:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	216	CA	HCFT7030IR	16 oz Sterile IPA w/ Flip Top	1119666-0-0-1	148351
102.000	60	CA	PSME0001-BPR	Clean Room Product	1130718-0-0-1	148351
103.000	60	CA	PSME0001	Clean Room Product	1128511-0-0-1	148351
	336	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	28.0 KGY	Pass	GLOORANDRA GONZALO LOOR ANDRADE	03/24/2025 14:55:32 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	50.0 kGy	37.7 KGY	Pass	GLOORANDRA GONZALO LOOR ANDRADE	03/24/2025 13:33:09 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: 03/24/2025 15:13:18 GMT