



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:	PSCS0009-BPR
Lot Number:	1118454-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	01/30/2025
Expiration Date:	01/2027

Analysis

% v/v Isopropyl Alcohol:	69.917
Quantity of Particles Po:	3.39 millions/m ²
Quantity of Fibers Po:	0.16 thousands/m ²
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²

Sterility

Gamma Processing Run ID:	3703632
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	29.2 kGy to 38.4 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
coc@contecinc.com

Tuesday, February 18, 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 Duplex
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

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DID: 20629A



Certificate of Processing

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

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02/17/2025 14:58:16 GMT
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Customer Name: Contec- PO Box 530
 P.O.# 147348

Processing Facility:

Charlotte Gamma

Work Order # 3703632
 Sales Order # 3736249

25-50 kGy

CNT6, Gamma Treatment

Irradiation Date/Time:

02/15/2025 21:30:00 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	1107269-0-0-1	147348
102.000	216	CA	HCFT7030IR	16 oz Sterile IPA w/ Flip Top	1107270-0-0-1	147348
103.000	216	CA	SB167030IR	16 oz IPA Spray Bottle 70/30	1113200-0-0-1	147348
104.000	216	CA	SB167030IR	16 oz IPA Spray Bottle 70/30	1113201-0-0-1	147348
105.000	72	CA	PSCS0009-BPR	Clean Room Product	1118454-0-0-1	147348
	936	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	MROSADO1	02/17/2025 14:18:24 GMT
		Reason Code Test				MARK ROSADO	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	38.4 KGY	Pass	MROSADO1	02/17/2025 14:18:41 GMT
		Reason Code Test				MARK ROSADO	

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: 02/17/2025 14:55:25 GMT