

## 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.

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Product Code:	PSWE0001-BPR
Lot Number:	1130764-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	03/13/2025
Expiration Date:	03/2027

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### Analysis

% v/v Isopropyl Alcohol:	70.039
Quantity of Particles Po 0.5µM:	3.59 millions/m <sup>2</sup>
Quantity of Fibers Po:	0.07 thousands/m <sup>2</sup>
Nonvolatile residue in DI:	0.0234 g/m <sup>2</sup>
Nonvolatile residue in IPA:	0.0019 g/m <sup>2</sup>
Endotoxin:	<0.533 EU/wipe

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### Sterility

Gamma Processing Run ID:	3731379
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	29.4 kGy to 42.0 kGy
Sterility Assurance Level:	10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137)

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QC Supervisor  
coc@contecinc.com

Tuesday, June 03, 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](http://www.contecinc.com)  
e-mail: [info@contecinc.com](mailto: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

04/02/2025 14:10:36 GMT  
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Customer Name: Contec- PO Box 530  
P.O.# 148541

Processing Facility: Charlotte Gamma

Work Order # 3731379  
Sales Order # 3769024

25-50 kGy

CNT7, Gamma Treatment

Irradiation Date/Time:

03/31/2025 16:23:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1133636-0-0-1	148541
102.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1133637-0-0-1	148541
103.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1133638-0-0-1	148541
104.000	108	CA	SB327030IR	32 oz IPA Spray Bottle 70/30	1133639-0-0-1	148541
105.000	108	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1133662-0-0-1	148541
106.000	108	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1133663-0-0-1	148541
107.000	108	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1133664-0-0-1	148541
108.000	108	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1133665-0-0-1	148541
109.000	72	CA	PSWE0001-BPR	Clean Room Products	1130764-0-0-1	148541
	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 Reason Code Test	50.0 kGy	29.4 KGY	Pass	GDIAZ FAUSTINO GERMAN DIAZ	04/01/2025 11:11:40 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	50.0 kGy	42.0 KGY	Pass	GDIAZ FAUSTINO GERMAN DIAZ	04/01/2025 11:11:53 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: 04/02/2025 14:08:58 GMT



## Kinetic LAL Analysis by USP

Charles River Laboratories, Inc.  
1023 Wappoo Road, Suite 43-B  
Charleston, South Carolina 29407 USA  
Phone: 843-402-4900  
Fax: 843-766-7576

Customer: Contec, Inc	CT#: 250488	Report Date: 30 May 2025
Product/Device: PSWE0001-BPR		
Lot#: 1130764-0-0-1		Units Received: 3
Potency: N/A	Endotoxin Limit: 1 EU/Wipe	MVD/MVC: 1:1000 Wipe/mL

### Reagent Information

Reagent	Lot#	Rehydration Date	Expires
Kinetic LAL	T4643E	30 May 2025	30 Sep 2027
Reference Standard Endotoxin	R172R0	28 May 2025	11 Jun 2025
LAL Reagent Water	52011124	N/A	30 Nov 2026

### Test Results

Sample Preparation: Place 3 wipes from a pack into beaker. Allow wipes to air dry in laminar flow hood for 2 hours. Add 200mL of LRW at 37°±1°C, and let extract at room temperature for one hour. Makes a 1:66. Further dilution made in LRW.			
Kinetic Method: Kinetic Chromogenic	Standard Curve Range: 5-0.001 EU/mL	Correlation Coefficient: -0.9991	Slope: -0.1870
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PSWE0001-BPR 1130764-0-0-1 (1 of 3)	1:533 Wipe/mL	<0.5330 EU/Wipe	CRL-2202100B- 20250530-002
PSWE0001-BPR 1130764-0-0-1 (2 of 3)	1:533 Wipe/mL	<0.5330 EU/Wipe	CRL-2202100B- 20250530-002
PSWE0001-BPR 1130764-0-0-1 (3 of 3)	1:533 Wipe/mL	<0.5330 EU/Wipe	CRL-2202100B- 20250530-002

Product/Device Lot: PSWE0001-BPR lot# 1130764-0-0-1		
Endotoxin Test : (Circle one) <u>PASS</u> FAIL		
Comments: (✓) N/A (Check N/A if not applicable)		
Analyst / Date: <i>J. Quitt</i> 30 May 2025	Reviewed By / Date: <i>A. Barney</i> 30 May 2025	QA Approved By / Date: <i>John E. Hall</i> 02 Jun 2025