

## 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:	PSWE0003-BPR
Lot Number:	1128331-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	03/06/2025
Expiration Date:	03/2027

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### Analysis

% v/v Isopropyl Alcohol:	70.048
Quantity of Particles Po 0.5µM:	5.2 millions/m <sup>2</sup>
Quantity of Fibers Po:	0.24 thousands/m <sup>2</sup>
Nonvolatile residue in DI:	0.0201 g/m <sup>2</sup>
Nonvolatile residue in IPA:	0.00 g/m <sup>2</sup>
Endotoxin:	<0.533 EU/wipe

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### Sterility

Gamma Processing Run ID:	3725211
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.2 kGy to 40.5 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

Friday, April 25, 2025

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## 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 15:03:54 GMT

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Customer Name: Contec- PO Box 530  
P.O.# 148275

Processing Facility: Charlotte Gamma

Work Order # 3725211  
Sales Order # 3761604

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

03/22/2025 18:14:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	30	CA	PSPS0077	Clean Room Product	1130084-0-0-1	148275
102.000	54	CA	PSPS0076	Clean Room Product	1125685-0-0-1	148275
103.000	36	CA	PSQS0001	Gamma Wipes	1129559-0-0-1	148275
104.000	72	CA	PSWE0003-BPR	PROSAT* PET 12X12 HF 70/30 IPA	1128331-0-0-1	148275
105.000	36	CA	PSQS0001	Gamma Wipes	1129759-0-0-1	148275
	228	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	27.2 KGY	Pass	DHOWELL	03/23/2025 04:26:24 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	40.5 KGY	Pass	DHOWELL	03/23/2025 04:26:38 GMT
		Reason Code Test				DEREK HOWELL	

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 15:02:21 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#: 250330	Report Date: 22 Apr 2025
Product/Device: PSWE0003-BPR		
Lot#: 1128331-0-0-1	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	22 Apr 2025	30 Sep 2027
Control Standard Endotoxin	EX54032 (RSE/CSE ratio = 14 EU/ng)	15 Apr 2025	31 Jan 2028
LAL Reagent Water	52011124 52070724 52100824	N/A	30 Nov 2026 30 Jul 2026 31 Aug 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: -0.9997	Slope: -0.2228
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PSWE0003-BPR 1128331-0-0-1      1 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1805145-20250422-002
PSWE0003-BPR 1128331-0-0-1      2 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1805145-20250422-002
PSWE0003-BPR 1128331-0-0-1      3 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1805145-20250422-002

Product/Device Lot: PSWE0003-BPR Lot#: 1128331-0-0-1		
Endotoxin Test : (Circle one)	<u>PASS</u>	FAIL
Comments: (✓) N/A (Check N/A if not applicable)		
Analyst / Date: <i>A. Schmitt</i> 22 Apr 2025	Reviewed By / Date: <i>A. Barney</i> 23 Apr 2025	QA Approved By / Date: <i>SLC</i> 24 Apr 2025