

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:	PSWE0003-BPR
Lot Number:	1133457-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	03/19/2025
Expiration Date:	03/2027

Analysis

% v/v Isopropyl Alcohol:	70.166
Quantity of Particles Po 0.5µM:	3.68 millions/m ²
Quantity of Fibers Po:	0.067 thousands/m ²
Nonvolatile residue in DI:	0.0519 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²
Endotoxin:	<0.533 EU/wipe

Sterility

Gamma Processing Run ID:	3732127
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	28.1 kGy to 40.2 kGy
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)



QC Supervisor
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Monday, April 21, 2025

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DID: 20632A

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#: 250286	Report Date: 16 Apr 2025
Product/Device: PSWE0003-BPR		
Lot#: 1133457-0-0-1	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	15 Apr 2025	30 Sep 2027
Reference Standard Endotoxin	R172R0	15 Apr 2025	29 Apr 2025
LAL Reagent Water	52011124 52100824 52041223	N/A	30 Nov 2026 31 Aug 2026 31 Dec 2025

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: -0.9995	Slope: -0.1978
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PSWE0003-BPR 1133457-0-0-1 1 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C-20250415-002
PSWE0003-BPR 1133457-0-0-1 2 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C-20250415-002
PSWE0003-BPR 1133457-0-0-1 3 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C-20250415-002

Product/Device Lot: PSWE0003-BPR Lot#: 1133457-0-0-1		
Endotoxin Test : (Circle one) <u>PASS</u> FAIL		
Comments: (<input checked="" type="checkbox"/>) N/A (Check N/A if not applicable)		
Analyst / Date: <i>Sean Robertson 16 Apr 2025</i>	Reviewed By / Date: <i>A. Bawey 16 Apr 2025</i>	QA Approved By / Date: <i>SLC 16 Apr 2025</i>

R55480102

03/31/2025 14:46:23 GMT

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 Customer Name: Contec- PO Box 530
 P.O.# 148567

Processing Facility: Charlotte Gamma

 Work Order # 3732127
 Sales Order # 3769989

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time: 03/29/2025 13:29:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	36	CA	PSQS0001	Gamma Wipes	1129765-0-0-1	148567
102.000	36	CA	PSQS0001	Gamma Wipes	1129766-0-0-1	148567
103.000	54	CA	PSPS0076	Clean Room Product	1130106-0-0-1	148567
104.000	54	CA	PSPS0076	Clean Room Product	1130107-0-0-1	148567
105.000	72	CA	PSWE0003-BPR	PROSAT* PET 12X12 HF 70/30 IPA	1133457-0-0-1	148567
	252	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	28.1 KGY	Pass	TDIAZ	03/29/2025 23:45:41 GMT
		Reason Code Test				Faustino (Tino) Diaz	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	40.2 KGY	Pass	TDIAZ	03/29/2025 23:46:09 GMT
		Reason Code Test				Faustino (Tino) Diaz	

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: 03/31/2025 14:42:52 GMT