

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:	PSWE0001-BPR
Lot Number:	1125731-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/26/2025
Expiration Date:	02/2027

Analysis

% v/v Isopropyl Alcohol:	69.963
Quantity of Particles Po 0.5µM:	4.02 millions/m ²
Quantity of Fibers Po:	0.039 thousands/m ²
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²
Endotoxin:	<0.533 EU/wipe

Sterility

Gamma Processing Run ID:	3722775
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	29.0 kGy to 42.9 kGy
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)



QC Supervisor
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Monday, March 31, 2025

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Page 1 of 1

DID: 20631A

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#: 250226	Report Date: 25 Mar 2025
Product/Device: PSWE0001-BPR		
Lot#: 1125731-0-0-1	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	R4822E	24 Mar 2025	30 Sep 2025
Reference Standard Endotoxin	R172R0	18 Mar 2025	01 Apr 2025
LAL Reagent Water	05322003	N/A	31 Mar 2025
LAL Reagent Water	52030423	N/A	30 Apr 2025
LAL Reagent Water	52031224	N/A	31 Dec 2026

Test Results

Sample Preparation: Place 3 wipes from a pack into beaker. Allow wipes to air dry 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: -0.9984	Slope: -0.1917
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PSWE0001-BPR 1125731-0-0-1 1 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1607192A-20250324-002
PSWE0001-BPR 1125731-0-0-1 2 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1607192A-20250324-002
PSWE0001-BPR 1125731-0-0-1 3 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-1607192A-20250324-002

Product/Device Lot: PSWE0001-BPR Lot# 1125731-0-0-1		
Endotoxin Test : (Circle one) <u>PASS</u> FAIL		
Comments: (<input checked="" type="checkbox"/>) N/A (Check N/A if not applicable)		
Analyst / Date: <i>Mya R</i> 25 Mar 2025	Reviewed By / Date: <i>A. Barney</i> 25 Mar 2025	QA Approved By / Date: <i>ML</i> 28 Mar 2025



Certificate of Processing

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

R55480102

03/18/2025 13:35:22 GMT

Page 1 of 1

Customer Name: Contec- PO Box 530
 P.O.# 148179

Processing Facility: Charlotte Gamma

Work Order # 3722775
 Sales Order # 3758774

25-50 kGy

CNT7, Gamma Treatment

Irradiation Date/Time:

03/17/2025 17:06:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	108	CA	HCTB3300IR	12x32oz One-Step Cleaner	1108235-0-0-1	148179
102.000	108	CA	HCTB3300IR	12x32oz One-Step Cleaner	1108236-0-0-1	148179
103.000	72	CA	PSWE0001-BPR	Clean Room Products	1125731-0-0-1	148179
104.000	72	CA	PSPS0091	Clean Room Product	1126693-0-0-1	148179
105.000	108	CA	HCTB3300IR	12x32oz One-Step Cleaner	1108237-0-0-1	148179
106.000	108	CA	HCTB3300IR	12x32oz One-Step Cleaner	1108238-0-0-1	148179
	576	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	29.0 KGY	Pass	MROSADO1	03/18/2025 13:11:08 GMT
		Reason Code Test				MARK ROSADO	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	42.9 KGY	Pass	GDIAZ	03/18/2025 07:53:37 GMT
		Reason Code Test				FAUSTINO GERMAN 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: WENDY KOBLISH
 Reason: Work Order Completions

Date: 03/18/2025 13:21:42 GMT