

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:	1127033-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/28/2025
Expiration Date:	02/2027

Analysis

% v/v Isopropyl Alcohol:	69.98
Quantity of Particles Po 0.5µM:	3.93 millions/m ²
Quantity of Fibers Po:	0.271 thousands/m ²
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.0077 g/m ²
Endotoxin:	<0.533 EU/wipe

Sterility

Gamma Processing Run ID:	3721853
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.2 kGy to 40.0 kGy
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)



QC Supervisor
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Monday, April 07, 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#: 250213	Report Date: 03 Apr 2025
Product/Device: PSWE0003-BPR		
Lot#: 1127033-0-0-1	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	31 Mar 2025	30 Sep 2027
Control Standard Endotoxin	EX54032 (RSE/CSE Ratio=14 EU/ng)	21 Mar 2025	31 Jan 2028
LAL Reagent Water	52030423 52031224	N/A	30 Apr 2025 31 Dec 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: -0.9998	Slope: -0.2045
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PSWE0003-BPR 1127033-0-0-1 1 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C- 20250331-002
PSWE0003-BPR 1127033-0-0-1 2 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C- 20250331-002
PSWE0003-BPR 1127033-0-0-1 3 of 3	1:533 wipe/mL	<0.5330 EU/wipe	CRL-2203141C- 20250331-002

Product/Device Lot: PSWE0003-BPR Lot#: 1127033-0-0-1		
Endotoxin Test : (Circle one) <u>PASS</u> FAIL		
Comments: (✓) N/A (Check N/A if not applicable)		
Analyst / Date: <u>Quinn Robertson 03 Apr 2025</u>	Reviewed By / Date: <u>A. Bamey 03 Apr 2025</u>	QA Approved By / Date: <u>XJC 03 Apr 2025</u>



Certificate of Processing

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

R55480102

03/10/2025 15:39:29 GMT
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Customer Name: Contec- PO Box 530 Processing Facility: Charlotte Gamma Work Order # 3721853
P.O.# 148160 Sales Order # 3757672

25-50 kGy

CNT1, Gamma Treatment

Irradiation Date/Time:

03/08/2025 20:36:00 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	1127689-0-0-1	148160
102.000	36	CA	PSQS0001	Gamma Wipes	1126703-0-0-1	148160
103.000	36	CA	PSQS0001	Gamma Wipes	1128310-0-0-1	148160
104.000	36	CA	PSQS0001	Gamma Wipes	1128311-0-0-1	148160
105.000	72	CA	PSWE0003-BPR	PROSAT* PET 12X12 HF 70/30 IPA	1127033-0-0-1	148160
106.000	360	CA	PSPP0039-BPR	Clean Room Product	1124303-0-0-1	148160
107.000	72	CA	PSWE0002	Clean Room Products	1129781-0-0-1	148160
	642	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	03/09/2025 09:40:04 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	40.0 KGY	Pass	DHOWELL	03/09/2025 09:40:17 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: WENDY KOBLISH
Reason: Work Order Completions

Date: 03/10/2025 15:25:14 GMT