



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:	PS-911LE
Lot Number:	693440-0-0-1
Description:	PROSAT sterile pre saturated wipes, low endotoxin
Manufacturing Date:	04/10/2019
Isopropyl Alcohol:	USP Grade 70 $\pm$ 3% by volume with the remainder DI H ₂ O
Expiration Date:	04/2021

Analysis

Quantity of Particles Po:	6.6 millions/m ²
Endotoxin:	<0.5330 EU/wipe

Sterility

Gamma Processing Run ID:	2420085
Irradiation Dose Specified:	18.20 kGy to 40 kGy
Irradiation Dose Delivered:	21.1 kGy to 32.4 kGy
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

QC Supervisor
coc@contecinc.com

Tuesday, May 07, 2019

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DID: 17021B

Certificate of Processing

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

R55480102

04/17/2019 13:46:46 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2420085
P.O.#	99675			Sales Order #	2212743
18.2-40.0 kGy		CNT4, Gamma Treatment	Irradiation Date/Time:	04/16/2019 07:07:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	8	CA	PS-911LE	Clean Room Product	693440-0-0-1	99675
102.000	384	CA	PS-911EB	Clean Room Product	691967-0-0-1	99675
103.000	180	CA	PS-911EB-12	Clean Room Product	696086-0-0-1	99675
104.000	96	CA	PS-911EB/ETOH	Clean Room Product	677828-0-0-1	99675
105.000	96	CA	PS-911EB/ETOH	Clean Room Product	677829-0-0-1	99675
	764	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	18.2 kGy	40.0 kGy	21.1 KGY	Pass	TDIAZ	04/16/2019 22:53:03 GMT
		Reason Code Test				Faustino (Tino) Diaz	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	32.4 KGY	Pass	TDIAZ	04/16/2019 22:53:17 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: WENDY KOBLISH
Reason: Work Order Completions

Date: 04/17/2019 13:46:18 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#: 190243	Report Date: 01 May 2019
Product/Device: PS-911LE		
Lot#: 693440-0-0-1		Units Received: 20
Potency: N/A	Endotoxin Limit: 20 EU/wipe	MVD/MVC: 1:20000 wipe/mL

Reagent Information

Reagent	Lot#	Rehydration Date	Expires
Kinetic LAL	K2323E	01 May 2019	Feb 2021
Control Standard Endotoxin	EX82043 (RSE/CSE ratio= 10 EU/ng)	26 Apr 2019	Aug 2021
LAL Reagent Water	02319001	N/A	Jan 2022
Other: N/A	N/A	N/A	N/A

Test Results

Sample Preparation: 3 wipes were taken from a pack, and placed in a depyrogenated beaker. The wipes were allowed to air dry in a laminar flow hood for 2 hours. Sample extracted in 200mL of LRW at 37°±1°C for one hour at room temperature making a 1:66 dilution. Further dilution in LRW.

Kinetic Method: Kinetic Chromogenic	Standard Curve Range: 5.0-0.001 EU/mL	Correlation Coefficient: -0.9953	Slope: -0.2002
Unit ID	Dilution Tested	Endotoxin Value	Datafile
PS-911LE 693440-0-0-1 1 of 3	1:533 wipe/mL	<0.5330 EU/wipe	223319050101.pltx
PS-911LE 693440-0-0-1 2 of 3	1:533 wipe/mL	<0.5330 EU/wipe	223319050101.pltx
PS-911LE 693440-0-0-1 3 of 3	1:533 wipe/mL	<0.5330 EU/wipe	223319050101.pltx

Product/Device Lot: PS-911LE Lot # 693440-0-0-1		
Endotoxin Test : (Circle one) PASS FAIL		
Comments: (x) N/A (Check N/A if not applicable)		
Analyst / Date: <i>SBH</i> 01 May 2019	Reviewed By / Date: <i>Bentim</i> 03 May 2019	QA Approved By / Date: <i>SL</i> 06 May 2019