

525 Locust Grove Spartanburg, SC 29303 864-503-8333 1-800-289-5762

fax 864-503-8444 www.contecinc.com

CERTIFICATE OF CONFORMANCE AND ANALYSIS AND **STERILITY**

Date: September 30, 2014

This certification is provided as full assurance that the following product code and lot number was manufactured in accordance with prescribed procedures and specifications

Product Code:

PS-911EB

Description:

PROSAT sterile pre saturated wipes

Lot Number:

371379-*-*-1

Manufacturing Date:

09/11/2014

Isopropyl Alcohol:

70 + -3% by volume with the remainder DI H20.

Quantity of Particles Po:

0.900 million 0.5 μm/m²

Run Number:

1370347

Irradiation Dose Specified: 18.2kGy to 40kGy Irradiation Dose Delivered: 20.8kGy to 33.2kGy

Validated Sterile Product: Validation Sterile packets available upon request.

Sterility Assurance Level: 10^-6 (SAL determined by test method

AAM1/ISO 11137)

Expiration Date:

09/2016

QC Supervisor coc@contecinc.com



Certificate of Processing

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

09/19/2014 18:03:46 GMT

Page 1 of 1

Customer Name: P.O.#

Contec-Box 530

66392

Processing Facility:

Charlotte Gamma

Work Order # Sales Order #

Cianad By

1370347 1196745

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

09/19/2014 07:49:08 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	128	CA	PS-911EB	Clean Room Product	HC369951-*-*-1	NA
102.000	128	CA	PS-911EB	Clean Room Product	371377-*-*-1	NA
103.000	128	CA	PS-911EB	Clean Room Product	371378-*-*-1	NA
104.000	128	CA	PS-911EB	Clean Room Product	371379-*-*-1	NA
105.000	2	CA	PS-7030IR	Clean Room Product	PT295-*-*-1	NA
106.000	2	CA	PS-7030IR	Clean Room Product	PT296-*-*-1	NA
107.000	4	CA	PS-7030IR	Clean Room Product	PT297-*-*-1	NA
	520	CA	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	18.2 kGy	40.0 kGy	20.8 KGY	Pass	SJDAVIS	09/19/2014 17:41:16 GMT
		Reason Code Test	:			STEVEN DAVIS	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	33.2 KGY	Pass	SJDAVIS	09/19/2014 17:41:37 GMT
		Reason Code Test	1			STEVEN DAVIS	

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: ALEX HERRINGTON

Reason: Work Order Completions

Date: 09/19/2014 17:56:47 GMT