

## 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-911EB** 

834906-0-0-1 Lot Number:

Description: PROSAT sterile pre saturated wipes

Manufacturing Date: 05/28/2021

Isopropyl Alcohol:  $70 \pm 3\%$  by volume with the remainder DI H2O.

05/2023 **Expiration Date:** 

**Analysis** 

5.015 millions/m<sup>2</sup> Quantity of Particles Po 0.5µM:

Sterility

Gamma Processing Run ID: 2898632

Irradiation Dose Specified: 18.2 kGy to 40 kGy Irradiation Dose Delivered: 21.8 kGy to 31.9 kGy

Validated Sterile Product: Validation Sterile packets available upon request.

Sterility Assurance Level: 10-6 (SAL determined by test method AAMI/ISO 11137)

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

R55480102

06/03/2021 12:47:32 GMT

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**Customer Name:** P.O.#

Contec-PO Box 530

118249

**Processing Facility:** 

Charlotte Gamma

Work Order # Sales Order # 2898632 2785981

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

06/02/2021 23:00:42 GMT

SO Line#	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
111.000	416	CA	PS-911EB	PROSAT Sterile Wipes	834905-0-0-1	118249
112.000	416	CA	PS-911EB	PROSAT Sterile Wipes	834906-0-0-1	118249
	832	CA	Total			

## **Quality Test Summary**

Ор#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	18.2 kGy Reason Code Test	40.0 kGy	21.8 KGY	Pass	DHOWELL DEREK HOWELL	06/03/2021 09:40:13 GMT
450.00	Maximum Dose	18.2 kGy Reason Code Test	40.0 kGy	31.9 KGY	Pass	DHOWELL DEREK HOWELL	06/03/2021 09:40:27 GMT

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: 06/03/2021 12:46:30 GMT