

## 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

Lot Number: 825682-0-0-1

Description: PROSAT sterile pre saturated wipes

Manufacturing Date: 03/31/2021

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

Expiration Date: 03/2023

**Analysis** 

Quantity of Particles Po 0.5µM: 4.4 millions/m<sup>2</sup>

Sterility

Gamma Processing Run ID: 2861462

Irradiation Dose Specified: 18.20 kGy to 40 kGy
Irradiation Dose Delivered: 21.3 kGy to 30.9 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

04/16/2021 12:43:42 GMT

Page 1 of 1

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

Contec- PO Box 530

116927

**Processing Facility:** 

Charlotte Gamma

Work Order # Sales Order # 2861462 2740274

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

04/15/2021 01:28:00 GMT

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7
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7

## **Quality Test Summary**

						Signed By		
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time	
450.00	Minimum Dose	18.2 kGy	40.0 kGy	21.3 KGY	Pass	MFREIBERG	04/16/2021 11:10:12 GMT	
		Reason Code Test				MICHAEL FREIBERG		
450.00	Maximum Dose	18.2 kGy	40.0 kGy	30.9 KGY	Pass	MFREIBERG	04/16/2021 11:10:24 GMT	
		Reason Code Test				MICHAEL FREIBERG		

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: 04/16/2021 12:40:23 GMT