

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: 823379-0-0-1

Description: PROSAT sterile pre saturated wipes

Manufacturing Date: 02/26/2021

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

02/2023 **Expiration Date:**

Analysis

6.439 millions/m² Quantity of Particles Po 0.5µM:

Sterility

Gamma Processing Run ID: 2840250

Irradiation Dose Specified: 18.20 kGy to 40 kGy Irradiation Dose Delivered: 21.2 kGy to 31.2 kGy

Validation Sterile packets available upon request. Validated Sterile Product:

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

03/12/2021 13:15:47 GMT

Page 1 of 1

Customer Name: P.O.#

Contec-PO Box 530

116213

Processing Facility:

Charlotte Gamma

Work Order # Sales Order# 2840250 2713985

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

03/11/2021 05:31:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number	
101.000	416	CA	PS-911EB	Clean Room Product	823379-0-0-1	116213	
102.000	270 686	CA CA	PS-911EB-12 Total	Clean Room Product	799050-0-0-1	116213	*

Quality Test Summary

Op#	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	21.2 KGY	Pass	DHOWELL DEREK HOWELL	03/11/2021 13:29:00 GMT
450.00	Maximum Dose	18.2 kGy Reason Code Test	40.0 kGy	31.2 KGY	Pass	DHOWELL DEREK HOWELL	03/11/2021 13:29:11 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: 03/12/2021 13:14:37 GMT