



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:	820138-0-0-1
Description:	PROSAT sterile pre saturated wipes
Manufacturing Date:	02/06/2021
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	02/2023

Analysis

Quantity of Particles Po 0.5µM:	12.646 millions/m ²
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Sterility

Gamma Processing Run ID:	2827270
Irradiation Dose Specified:	18.20 kGy to 40 kGy
Irradiation Dose Delivered:	20.2 kGy to 31.3 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

Friday, February 19, 2021

NORTH AMERICA

Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA
tel: +1 864 503 8333
fax: +1 864 503 8444

EUROPE

Contec Europe
ZI Du Prat, Avenue Paul Duplex
56000 VANNES France
tel: +33 (0)2 97 43 76 98
fax: +33 (0) 97 43 76 86

ASIA

Contec Cleanroom Technology (Suzhou) Co., Ltd.
17 Longyun Road
Suzhou Industrial Park, Suzhou 215024 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

web: www.contecinc.com
e-mail: info@contecinc.com

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DID: 221C



Certificate of Processing

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

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Customer Name: Contec- PO Box 530
P.O.# 115741

Processing Facility:

Charlotte Gamma

Work Order # 2827270
Sales Order # 2697696

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

02/18/2021 08:18:00 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	820138-0-0-1	115741
102.000	416	CA	PS-911EB	Clean Room Product	820139-0-0-1	115741
	832	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	20.2 KGY	Pass	TDIAZ	02/18/2021 18:45:45 GMT
	Reason Code Test					Faustino (Tino) Diaz	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	31.3 KGY	Pass	TDIAZ	02/18/2021 18:46:00 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: BRITTANY LONG
Reason: Work Order Completions

Date: 02/19/2021 13:50:01 GMT