

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-BPR
Lot Number:	1118873-0-0-1
Description:	PROSAT sterile pre saturated wipes
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/25/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	02/2027

Analysis

Quantity of Particles Po 0.5µM:	1.999 millions/m ²
---------------------------------	-------------------------------

Sterility

Gamma Processing Run ID:	3716861
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	19.6 kGy to 35.0 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

Tuesday, March 11, 2025

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 Dupleix
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

Page 1 of 1

DID: 20602A



Certificate of Processing

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

R55480102

03/05/2025 14:06:55 GMT
 Page 1 of 1

Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3716861
P.O.#	147949			Sales Order #	3751543
18.2-40.0 kGy		CNT4, Gamma Treatment	Irradiation Date/Time:	03/04/2025 17:50:05 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	414	CA	PS-911EB	PROSAT Sterile Wipes	1118866-0-0-1	147949
102.000	414	CA	PS-911EB-BPR	PROSAT Sterile Wipes	1118873-0-0-1	147949
	828	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	19.6 KGY	Pass	DHOWELL	03/05/2025 04:21:46 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	35.0 KGY	Pass	DHOWELL	03/05/2025 04:21:59 GMT
		Reason Code Test				DEREK HOWELL	

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: 03/05/2025 14:05:14 GMT