



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:	1128468-0-0-1
Description:	PROSAT sterile pre saturated wipes
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/28/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O.
Expiration Date:	02/2027

Analysis

Quantity of Particles Po 0.5µM:	19.596 millions/m ²
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Sterility

Gamma Processing Run ID:	3719434
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	20.2 kGy to 33.2 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
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Wednesday, March 12, 2025

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DID: 20602A



Certificate of Processing

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03/07/2025 15:47:48 GMT

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Customer Name: Contec- PO Box 530
P.O.# 148033

Processing Facility:

Charlotte Gamma

Work Order # 3719434
Sales Order # 3754914

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

03/07/2025 01:11:00 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	1118869-0-0-1	148033
102.000	414	CA	PS-911EB-BPR	PROSAT Sterile Wipes	1128468-0-0-1	148033
	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	20.2 KGY	Pass	GDIAZ	03/07/2025 13:52:14 GMT
		Reason Code Test				FAUSTINO GERMAN DIAZ	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	33.2 KGY	Pass	GDIAZ	03/07/2025 13:52:32 GMT
		Reason Code Test				FAUSTINO GERMAN 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: 03/07/2025 15:46:50 GMT