

Certificate of Conformance 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-7030IR-BPR
Lot Number:	1107248-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	04/23/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	04/2027

Sterility

Gamma Processing Run ID:	3752342
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	21.7 kGy to 31.6 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

The expiration date is the date of manufacture plus two years.



QC Supervisor
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Thursday, May 01, 2025

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Certificate of Processing

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04/30/2025 14:39:43 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3752342
P.O.#	149429			Sales Order #	3794853
	18.2-40.0 kGy	CNT4, Gamma Treatment	Irradiation Date/Time:	04/29/2025 13:08:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	240	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	1107248-0-0-1	149429
102.000	240	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	1125898-0-0-1	149429
	480	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 Reason Code Test	40.0 kGy	21.7 KGY	Pass	GLOORANDRA GONZALO LOOR ANDRADE	04/30/2025 13:17:14 GMT
450.00	Maximum Dose	18.2 kGy Reason Code Test	40.0 kGy	31.6 KGY	Pass	GLOORANDRA GONZALO LOOR ANDRADE	04/30/2025 13:17:28 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: 04/30/2025 14:37:57 GMT