

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:	1135860-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	06/09/2025
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	06/2027

Sterility

Gamma Processing Run ID:	3779685
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	23.1 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)

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



QC Supervisor
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Tuesday, June 17, 2025

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Certificate of Processing

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Customer Name: Contec- PO Box 530
P.O.# 150616

Processing Facility:

Charlotte Gamma

Work Order # 3779685
Sales Order # 3828577

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

06/13/2025 01:20:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	280	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	1135860-0-0-1	150616
102.000	120	CA	PS-7030IR	Clean Room Product	1151094-0-0-1	150616
	400	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	23.1 KGY	Pass	MROSADO1 MARK ROSADO	06/13/2025 17:48:43 GMT
450.00	Maximum Dose	18.2 kGy	40.0 kGy	35.0 KGY	Pass	MROSADO1 MARK ROSADO	06/13/2025 17:49:04 GMT
		Reason Code Test					

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: WENDY KOBLISH
Reason: Work Order Completions

Date: 06/13/2025 19:39:51 GMT