

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:	1091597-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	12/09/2024
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	12/2026

Sterility

Gamma Processing Run ID:	3675454
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	20.8 kGy to 32.0 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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Monday, December 23, 2024

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Certificate of Processing

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Customer Name: Contec- PO Box 530
P.O.# 146094

Processing Facility:

Charlotte Gamma

Work Order # 3675454
Sales Order # 3701363

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

12/17/2024 15:57:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	96	CA	PS-840IR	MBPP Nonwoven 70/30 IPA Wipes	1098570-0-0-1	146094
102.000	280	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	1091597-0-0-1	146094
	376	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	20.8 KGY	Pass	MROSADO1	12/18/2024 13:08:20 GMT
		Reason Code Test				MARK ROSADO	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	32.0 KGY	Pass	MPAPADIM	12/18/2024 01:49:19 GMT
		Reason Code Test				MANOLIS	
						PAPADIMITRIOU	

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: 12/19/2024 13:31:34 GMT