



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:	1001950-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	08/16/2023
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	08/2025

Sterility

Gamma Processing Run ID:	3400639
Irradiation Dose Specified:	18.2 kGy to 40.0 kGy
Irradiation Dose Delivered:	20.9 kGy to 31.7 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, August 29, 2023

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DID: 20615A



Certificate of Processing

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08/24/2023 13:17:17 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3400639
P.O.#	135400			Sales Order #	3374381
18.2-40.0 kGy		CNT4, Gamma Treatment	Irradiation Date/Time:	08/22/2023 23:27:34 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	400	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	1001950-0-0-1	135400
102.000	240	CA	PS-7030IR	Clean Room Product	1002678-0-0-1	135400
	640	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	20.9 KGY	Pass	DHOWELL	08/23/2023 10:53:21 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	31.7 KGY	Pass	DHOWELL	08/23/2023 10:57:46 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: 08/24/2023 13:16:42 GMT