



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:	908113-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	02/08/2022
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	02/2024

Sterility

Gamma Processing Run ID:	3058528
Irradiation Dose Specified:	18.2 kGy to 40 kGy
Irradiation Dose Delivered:	22.7 kGy to 34.8 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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Friday, February 18, 2022

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DID: 20615A



Certificate of Processing

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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3058528
P.O.#	123603			Sales Order #	2973904
	18.2-40.0 kGy	CNT4, Gamma Treatment	Irradiation Date/Time:		02/16/2022 12:43:00 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	906041-0-0-1	123603
102.000	160	CA	PS-7030IR-BPR	PROSAT Sterile Wipes	908113-0-0-1	123603
	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	22.7 KGY	Pass	BTOWERY Benjamin Towery	02/17/2022 01:53:33 GMT
450.00	Maximum Dose	18.2 kGy	40.0 kGy	34.8 KGY	Pass	BTOWERY Benjamin Towery	02/17/2022 01:54:01 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: 02/17/2022 13:43:47 GMT