



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:	928821-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	05/10/2022
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	05/2024

Sterility

Gamma Processing Run ID:	3118863
Irradiation Dose Specified:	18.2 kGy to 40 kGy
Irradiation Dose Delivered:	21.3 kGy to 33.3 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
coc@contecinc.com

Tuesday, May 24, 2022

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DID: 20615A



Certificate of Processing

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Customer Name: Contec- PO Box 530
P.O.# 125547

Processing Facility:

Charlotte Gamma

Work Order # 3118863
Sales Order # 3043920

18.2-40.0 kGy

CNT4, Gamma Treatment

Irradiation Date/Time:

05/18/2022 11:41:00 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	928821-0-0-1	125547
	240	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	21.3 KGY	Pass	TDIAZ	05/18/2022 22:31:36 GMT
	Reason Code Test					Faustino (Tino) Diaz	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	33.3 KGY	Pass	TDIAZ	05/18/2022 22:31:53 GMT
	Reason Code Test					Faustino (Tino) Diaz	

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: 05/19/2022 13:34:48 GMT