



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
Lot Number:	723809-0-0-1
Manufacturing Date:	08/29/2019
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	08/2021

Sterility

Gamma Processing Run ID:	2508889
Irradiation Dose Specified:	18.20 kGy to 40 kGy
Irradiation Dose Delivered:	20.3 kGy to 31.3 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. If you have any questions please contact us.

QC Supervisor
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Monday, September 09, 2019

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Customer Name: Contec- PO Box 530	Processing Facility: Charlotte Gamma	Work Order # 2508889
P.O.# 102989		Sales Order # 2315785
18.2-40.0 kGy	CNT4, Gamma Treatment	Irradiation Date/Time: 09/04/2019 03:56:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	248	CA	PS-7030IR	Clean Room Product	723809-0-0-1	102989
102.000	120	CA	PS-7030IR	Clean Room Product	723810-0-0-1	102989
	368	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	20.3 KGY	Pass	TDIAZ	09/04/2019 18:42:06 GMT
	Reason Code Test					Faustino (Tino) Diaz	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	31.3 KGY	Pass	TDIAZ	09/04/2019 18:42:21 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: WENDY KOBLISH
Reason: Work Order Completions

Date: 09/05/2019 14:48:10 GMT