



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:	705236-0-0-1
Manufacturing Date:	06/05/2019
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	06/2021

Sterility

Gamma Processing Run ID:	2454699
Irradiation Dose Specified:	18.20 kGy to 40 kGy
Irradiation Dose Delivered:	20.2 kGy to 31.6 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
coc@contecinc.com

Tuesday, June 18, 2019

NORTH AMERICA

Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA
tel: +1 864 503 8333
fax: +1 864 503 8444

EUROPE

Contec, Inc.
ZI du Prat - R.P. 3707
F-56037 VANNES Cedex France
tel: +33 (0)2 97 43 76 98
fax: +33 (0) 97 43 76 86

ASIA

Contec Cleanroom Technology (Suzhou) Co., Ltd.
17 Longyun Road
Suzhou Industrial Park, Suzhou 215024 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

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web: www.contecinc.com
e-mail: info@contecinc.com

Certificate of Processing

STERIGENICS 10811 Withers Cove Park Dr. Charlotte NC 28278
TEL 704 588-6877 FAX 704 588-8355 www.sterigenics.com

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06/12/2019 14:08:47 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2454699
P.O.#	100940			Sales Order #	2253173
	18.2-40.0 kGy	CNT4, Gamma Treatment	Irradiation Date/Time:	06/11/2019 08:43:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	300	CA	PS-7030IR	Clean Room Product	705236-0-0-1	100940
	300	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	20.2 KGY	Pass	SJDAVIS	06/12/2019 13:38:33 GMT
		Reason Code Test				STEVEN DAVIS	
450.00	Maximum Dose	18.2 kGy	40.0 kGy	31.6 KGY	Pass	SJDAVIS	06/12/2019 13:38:43 GMT
		Reason Code Test				STEVEN DAVIS	

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: 06/12/2019 14:07:30 GMT