



Certificate of Conformance, Analysis, 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:	PSPS0093
Lot Number:	801610-0-0-1
Manufacturing Date:	09/11/2020
Expiration Date:	09/2022

Analysis

% v/v Isopropyl Alcohol:	69.998
Quantity of Particles Po:	3.29 millions/m ²
Quantity of Fibers Po:	0.177 thousands/m ²
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²

Sterility

Gamma Processing Run ID:	2742248
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	29.8 kGy to 42.5 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

QC Supervisor
coc@contecinc.com

Tuesday, September 29, 2020

NORTH AMERICA

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

Page 1 of 1

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

DID: 10241B



Certificate of Processing

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

R55480102

09/28/2020 13:30:46 GMT
 Page 1 of 1

Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2742248
P.O.#	112438			Sales Order #	2593760
	25-50 kGy	CNT6, Gamma Treatment	Irradiation Date/Time:		09/25/2020 18:34:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	60	CA	PSME0001	Clean Room Product	802346-0-0-1	112438
102.000	60	CA	PSME0001	Clean Room Product	802347-0-0-1	112438
103.000	60	CA	PSME0001	Clean Room Product	802348-0-0-1	112438
104.000	72	CA	PSPS0093	Clean Room Product	801610-0-0-1	112438
105.000	72	CA	PSPS0093	Clean Room Product	802208-0-0-1	112438
	324	CA	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	Signed By	Date /Time
450.00	Minimum Dose	25.0 kGy	50.0 kGy	29.8 KGY	Pass	MFREIBERG	09/26/2020 16:10:56 GMT
		Reason Code Test				MICHAEL FREIBERG	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	42.5 KGY	Pass	MFREIBERG	09/26/2020 16:11:06 GMT
		Reason Code Test				MICHAEL FREIBERG	

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: 09/28/2020 13:23:24 GMT