



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:	PSPS0091-BPR
Lot Number:	1003773-0-0-1
EU BPR Authorisation Number:	EU-0020460 0002 (1-2)
Manufacturing Date:	07/06/2023
Expiration Date:	07/2025

Analysis

Quantity of Particles Po:	3.1 millions/m ²
Quantity of Fibers Po:	0.125 thousands/m ²
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.00 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²

Sterility

Gamma Processing Run ID:	3378137
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.7 kGy to 41.6 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

Wednesday, July 19, 2023

NORTH AMERICA

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

EUROPE

Contec Europe
ZI Du Prat, Avenue Paul Duplex
56000 VANNES 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

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

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DID: 20633A

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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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	3378137
P.O.#	134546			Sales Order #	3347958
25-50 kGy		CNT1, Gamma Treatment	Irradiation Date/Time:	07/15/2023 23:18:44 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	54	CA	PSPS0076	Clean Room Product	1000693-0-0-1	134546
102.000	72	CA	PSPS0091-BPR	Clean Room Product	1003773-0-0-1	134546
103.000	72	CA	PSPS0091-BPR	Clean Room Product	1003774-0-0-1	134546
104.000	36	CA	PSCS0012	Clean Room Product	1003575-0-0-1	134546
105.000	468	CA	PSC20005	Clean Room Product	998953-0-0-1	134546
106.000	72	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1000691-0-0-1	134546
107.000	72	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1003697-0-0-1	134546
108.000	72	CA	HCFT7030IR_32	32 oz Sterile IPA w/ cap	1003698-0-0-1	134546
	918	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	25.0 kGy	50.0 kGy	27.7 KGY	Pass	DHOWELL	07/16/2023 12:55:51 GMT
		Reason Code Test				DEREK HOWELL	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	41.6 KGY	Pass	DHOWELL	07/16/2023 12:56:03 GMT
		Reason Code Test				DEREK HOWELL	

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: 07/17/2023 15:53:56 GMT