



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:	PSQS0001
Lot Number:	799998-0-0-1
Manufacturing Date:	08/31/2020
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	08/2022

Analysis

Quantity of Particles Po:	2.88 millions/m ²
Quantity of Fibers Po:	0.701 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:	2733236
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	29.9 kGy to 44.8 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
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Monday, November 30, 2020

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DID: 2201B



Certificate of Processing

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09/14/2020 14:44:06 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2733236
P.O.#	112125			Sales Order #	2583214
25-50 kGy		CNT1, Gamma Treatment	Irradiation Date/Time:	09/11/2020 18:48:00 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	800457-0-0-1	112125
102.000	36	CA	PSQS0001	Gamma Wipes	799998-0-0-1	112125
103.000	36	CA	PSQS0001	Gamma Wipes	799999-0-0-1	112125
	126	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	29.9 KGY	Pass	MFREIBERG	09/12/2020 16:06:25 GMT
		Reason Code Test				MICHAEL FREIBERG	
450.00	Maximum Dose	25.0 kGy	50.0 kGy	44.8 KGY	Pass	MFREIBERG	09/12/2020 16:06:36 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: 09/14/2020 14:37:01 GMT