



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:	795054-0-0-1
Manufacturing Date:	08/11/2020
Isopropyl Alcohol:	70 ± 3% by volume with the remainder DI H2O
Expiration Date:	08/2022

Analysis

Quantity of Particles Po:	4.45 millions/m ²
Quantity of Fibers Po:	0.14 thousands/m ²
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.0029 g/m ²
Nonvolatile residue in IPA:	0.00 g/m ²

Sterility

Gamma Processing Run ID:	2721859
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	28.8 kGy to 43.6 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
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Tuesday, August 25, 2020

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DID: 2201B



Certificate of Processing

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08/24/2020 13:35:56 GMT
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Customer Name:	Contec- PO Box 530	Processing Facility:	Charlotte Gamma	Work Order #	2721859
P.O.#	111580			Sales Order #	2568869
25-50 kGy		CNT1, Gamma Treatment	Irradiation Date/Time:	08/22/2020 13:31:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	108	CA	89499-420	STERILE 70% IPA/ 30% DI 32 OZ	786328-0-0-1	111580
102.000	108	CA	89499-420	STERILE 70% IPA/ 30% DI 32 OZ	786329-0-0-1	111580
103.000	54	CA	PSPS0076	Clean Room Product	795019-0-0-1	111580
104.000	54	CA	PSPS0076	Clean Room Product	795020-0-0-1	111580
105.000	72	CA	PSPS0091	Clean Room Product	795042-0-0-1	111580
106.000	36	CA	PSQS0001	Gamma Wipes	795054-0-0-1	111580
	432	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	28.8 KGY	Pass	BTOWERY Benjamin Towery	08/23/2020 02:30:08 GMT
450.00	Maximum Dose	25.0 kGy	50.0 kGy	43.6 KGY	Pass	BTOWERY Benjamin Towery	08/23/2020 02:33:26 GMT
	Reason Code Test						

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: 08/24/2020 13:30:29 GMT