



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:	495353-322
Lot Number:	796374-0-0-1
Manufacturing Date:	08/26/2020
Expiration Date:	08/2022

Analysis

Biaxial Shake Fibers:	0.251 thousands/m ²
Biaxial Shake Particles 0.5µM:	9.7 millions/m ²
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.0051 g/m ²
Nonvolatile residue in IPA:	0.0104 g/m ²

Sterility

Gamma Processing Run ID:	58567A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	27.0 kGy to 42.8 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
coc@contecinc.com

Monday, November 30, 2020

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DID: 16001B

Certificate Of Processing

Prepared for **CONTEC INC**



Gamma Process Run ID **58567A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
495353-322	796374-0-0-1	36	CS
76377-480	798375-0-0-1	48	CS
76377-480	798376-0-0-1	48	CS
HCPM5051	797834-0-0-1	54	CS
LWCS0027	799814-0-0-1	36	CS
LWPS0007	798389-0-0-1	20	CS
LWPS0027	799843-0-0-1	36	CS
LWQS0002	798428-0-0-1	36	CS
LWQT0031	799902-0-0-1	20	CS

Processing Run Start Date/Time: 05-Sep-2020 06:16:10 am Approx. Downtime (hours): 0.20
Processing Run End Date/Time: 05-Sep-2020 01:23:58 pm

Minimum Specified Dose (kGy): 25.0 Minimum Delivered Dose (kGy): 27.0
Maximum Specified Dose (kGy): 50.0 Maximum Delivered Dose (kGy): 42.8

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest



Reviewed and E-Signed By
Danny Vassey (QS & RC Technician I)
Document Content Revision: 1

Signed On 9/8/2020 at 8:42 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:

STERIS
2072 Southport Road
Spartanburg, SC 29306
Phone: 864-582-3041
Fax: 864-582-4075

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.