



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:	793750-0-0-1
Manufacturing Date:	08/06/2020
Expiration Date:	08/2022

Analysis

Biaxial Shake Fibers:	0.065 thousands/m ²
Biaxial Shake Particles 0.5µM:	7.6 millions/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:	58437A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	31.5 kGy to 45.4 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, August 17, 2020

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DID: 16001B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID **58437A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
495353-322	793750-0-0-1	35	CS
495353-323	793860-0-0-1	36	CS
EL-MOP-IR	790704-0-0-1	18	CS
LWPS0027	794848-0-0-1	36	CS
MEQT0002	794891-0-0-1	72	CS
PN-99IR	793821-0-0-1	26	CS
PN-99IR	793873-0-0-1	26	CS

Processing Run Start Date/Time:	14-Aug-2020 09:47:31 pm	Approx. Downtime (hours):	0.90
Processing Run End Date/Time:	15-Aug-2020 05:11:29 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	31.5
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	45.4

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

Signature Manifest



Reviewed and E-Signed By
Brandie McCurry (QS/RC Technician)
Document Content Revision: 1

Signed On 8/17/2020 at 8:51 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.