



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:	792317-0-0-1
Manufacturing Date:	07/27/2020
Expiration Date:	07/2022

Analysis

Biaxial Shake Fibers:	0.06 thousands/m ²
Biaxial Shake Particles 0.5µM:	9.0 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:	58348A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	28.7 kGy to 40.7 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 04, 2020

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DID: 16001B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID **58348A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
492238-960	792309-0-0-1	32	CS
495353-322	792317-0-0-1	36	CS
ELMOP3IR	784426-0-0-1	60	CS
MEQT0012	792174-0-0-1	72	CS

Processing Run Start Date/Time:	01-Aug-2020 09:41:02 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	02-Aug-2020 04:09:42 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	28.7
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	40.7

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 8/3/2020 at 7:30 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.