



Certificate of Conformance 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:	MEQT0022
Lot Number:	787002-0-0-1
Manufacturing Date:	06/24/2020
Expiration Date:	06/2022

Sterility

Gamma Processing Run ID:	58311A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	29.5 kGy to 42.9 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

A handwritten signature in black ink, appearing to read "C. Duffee".

QC Supervisor
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Monday, July 27, 2020

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DID: 20498A

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID **58311A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
492226-939	789912-0-0-1	18	CS
492226-939	789913-0-0-1	17	CS
492238-960	791070-0-0-1	32	CS
76377-480	790700-0-0-1	48	CS
EL-MOP-IR	784420-0-0-1	18	CS
GOGLIR	784013-0-0-1	171	CS
LWPS0027	789945-0-0-1	36	CS
LWPS0027	790613-0-0-1	36	CS
LWPS0027	790614-0-0-1	36	CS
LWPS0027	790691-0-0-1	36	CS
MEQT0002	790639-0-0-1	72	CS
MEQT0012	790644-0-0-1	72	CS
MEQT0022	787002-0-0-1	48	CS

Processing Run Start Date/Time: 24-Jul-2020 04:20:56 pm

Approx. Downtime (hours): 0.20

Processing Run End Date/Time: 25-Jul-2020 01:00:45 am

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	29.5
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	42.9

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 7/27/2020 at 7:04 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.