



Certificate of Conformance and Irradiation

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:	BKTBAG
Lot Number:	706904-0-0-1
Manufacturing Date:	06/26/2019
Expiration Date:	06/2021

Irradiation

Gamma Processing Run ID:	55656A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	30.8 kGy to 46.5 kGy

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

QC Supervisor
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Wednesday, July 17, 2019

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Page 1 of 1

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DID: 11441B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55656A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
33502-730	712878-0-0-1	24	CS
492226-939	712339-0-0-1	36	CS
492226-942	712678-0-0-1	36	CS
492238-960	712188-0-0-1	32	CS
BKT BAG	706904-0-0-1	48	CS
ELMOP3IR	711716-0-0-1	60	CS
MEQT0002	713465-0-0-1	72	CS
MEQT0002	713466-0-0-1	72	CS

Processing Run Start Date/Time:	11-Jul-2019 05:37:59 pm	Approx. Downtime (hours):	0.20
Processing Run End Date/Time:	12-Jul-2019 01:46:38 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	30.8
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	46.5

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 7/12/2019 at 9:06 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.