



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:	690352-0-0-1
Manufacturing Date:	05/01/2019
Expiration Date:	05/2021

Irradiation

Gamma Processing Run ID:	55141A
Irradiation Dose Specified:	25 kGy to 50 kGy
Irradiation Dose Delivered:	31.0 kGy to 46.5 kGy

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

QC Supervisor
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Monday, May 06, 2019

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Page 1 of 1

DID: 11441B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55141A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
21914-772	698990-0-0-1	48	CS
BKTBAG	688033-0-0-1	48	CS
BKTBAG	690352-0-0-1	48	CS
EL-MOP-IR	698064-0-0-1	18	CS
EL-MOP-IR	698065-0-0-1	18	CS
LWPS0027	696226-0-0-1	36	CS
LWPS0027	696227-0-0-1	36	CS
MEQT0002	701409-0-0-1	72	CS
MEQT0002	701410-0-0-1	72	CS
PN-99IR	701360-0-0-1	26	CS

Processing Run Start Date/Time:	05-May-2019 12:57:40 am	Approx. Downtime (hours):	0.70
Processing Run End Date/Time:	05-May-2019 09:10:46 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	31.0
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
Pachy Thor (QA Analyst)
Document Content Revision: 1

Signed On 5/5/2019 at 12:15 PM
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.