



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:	VKMX0375
Lot Number:	739551-0-0-1
Manufacturing Date:	11/12/2019
Expiration Date:	11/2021

Sterility

Gamma Processing Run ID:	56589A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.1 kGy to 46.3 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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Thursday, November 21, 2019

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DID: 15461B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56589A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
EZMP0350	738411-0-0-1	16	CS
EZMP0350	739292-0-0-1	16	CS
EZMP0350	739303-0-0-1	16	CS
HCKM3053	739293-0-0-1	24	CS
HCKM3053	739295-0-0-1	24	CS
HCKM3053	739296-0-0-1	24	CS
HCKM3054	738354-0-0-1	24	CS
LVK-MOP-IR	737868-0-0-1	18	CS
VKMX0275	739241-0-0-1	24	CS
VKMX0275	739242-0-0-1	24	CS
VKMX0275	739243-0-0-1	24	CS
VKMX0375	739551-0-0-1	24	CS
VKMX0375	739552-0-0-1	24	CS
VKSE0250	738358-0-0-1	24	CS

Processing Run Start Date/Time:	17-Nov-2019 05:26:22 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	18-Nov-2019 01:37:08 am		

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	33.1
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	46.3

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 11/19/2019 at 8:14 AM

UTC / GMT Offset (hh:mm): -5:00

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.