



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:	VKMX0275
Lot Number:	697191-0-0-1
Manufacturing Date:	07/16/2019
Expiration Date:	07/2021

Sterility

Gamma Processing Run ID:	55707A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	34.8 kGy to 47.1 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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Wednesday, July 24, 2019

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Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55707A


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BLVKMOPIR	716907-0-0-1	18	CS
VK-MOP-IR	715806-0-0-1	18	CS
VKMX0275	697190-0-0-1	24	CS
VKMX0275	697191-0-0-1	24	CS
VKMX0375	680809-0-0-1	24	CS
VKMX0375	690777-0-0-1	24	CS
VKMX0375	690779-0-0-1	24	CS
VKSE0150	712857-0-0-1	27	CS
VKSE0250	715952-0-0-1	24	CS
VKSE0250	716916-0-0-1	24	CS
VKSE0250	716917-0-0-1	24	CS
VKSE0250	716918-0-0-1	24	CS
VKSE0250	716919-0-0-1	24	CS
VKSE0250	716920-0-0-1	24	CS
VKSE0250	716921-0-0-1	24	CS
VKSE0250	716922-0-0-1	24	CS
VKSE0250	716923-0-0-1	24	CS

Processing Run Start Date/Time: 21-Jul-2019 09:26:50 pm Approx. Downtime (hours): 0.90
Processing Run End Date/Time: 22-Jul-2019 06:56:39 am

Minimum Specified Dose (kGy): 30.0	Minimum Delivered Dose (kGy): 34.8
Maximum Specified Dose (kGy): 50.0	Maximum Delivered Dose (kGy): 47.1

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 7/23/2019 at 6:41 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.

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55707A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VKSE0250	716924-0-0-1	24	CS
VKSE0250	716925-0-0-1	24	CS
VKSE0250	716926-0-0-1	24	CS

Processing Run Start Date/Time: 21-Jul-2019 09:26:50 pm Approx. Downtime (hours): 0.90
Processing Run End Date/Time: 22-Jul-2019 06:56:39 am

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Maximum Specified Dose (kGy): 50.0	Maximum Delivered Dose (kGy): 47.1

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