



## 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.

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Product Code:	VKMX0275
Lot Number:	696442-0-0-1
Manufacturing Date:	04/16/2019
Expiration Date:	04/2021

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### Sterility

Gamma Processing Run ID:	55080A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.4 kGy to 46.8 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137)

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QC Supervisor  
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Thursday, May 02, 2019

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# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55080A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
TLVKMOPIR	685922-0-0-1	18	CS
TLVKMOPIR	690514-0-0-1	18	CS
TLVKMOPIR	690515-0-0-1	18	CS
TLVKMOPIR	690516-0-0-1	18	CS
TLVKMOPIR	697177-0-0-1	18	CS
VK-MOP-IR	697181-0-0-1	18	CS
VK-MOP-IR	697182-0-0-1	18	CS
VKMX0275	696058-0-0-1	24	CS
VKMX0275	696440-0-0-1	24	CS
VKMX0275	696441-0-0-1	24	CS
VKMX0275	696442-0-0-1	24	CS
VKSE0250	692512-0-0-1	24	CS
VKSE0250	692513-0-0-1	24	CS
VKSE0250	692514-0-0-1	24	CS
VKSE0250	692515-0-0-1	24	CS
VKSE0250	692516-0-0-1	24	CS
VKSE0250	698499-0-0-1	24	CS

Processing Run Start Date/Time: 27-Apr-2019 04:02:29 pm      Approx. Downtime (hours): 0.60  
Processing Run End Date/Time: 28-Apr-2019 12:57:56 am

<b>Minimum Specified Dose (kGy):</b> 30.0	<b>Minimum Delivered Dose (kGy):</b> 33.4
<b>Maximum Specified Dose (kGy):</b> 50.0	<b>Maximum Delivered Dose (kGy):</b> 46.8

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 4/30/2019 at 1:34 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.

# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55080A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VKSE0250	698500-0-0-1	24	CS

Processing Run Start Date/Time:	27-Apr-2019 04:02:29 pm	Approx. Downtime (hours):	0.60
Processing Run End Date/Time:	28-Apr-2019 12:57:56 am		

<b>Minimum Specified Dose (kGy):</b>	<b>30.0</b>	<b>Minimum Delivered Dose (kGy):</b>	<b>33.4</b>
<b>Maximum Specified Dose (kGy):</b>	<b>50.0</b>	<b>Maximum Delivered Dose (kGy):</b>	<b>46.8</b>

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

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