



## 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:	EZMP0350
Lot Number:	713134-0-0-1
Manufacturing Date:	09/30/2019
Expiration Date:	09/2021

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### Sterility

Gamma Processing Run ID:	56260A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.1 kGy to 45.0 kGy
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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Wednesday, October 09, 2019

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# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56260A


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
EZMP0350	713134-0-0-1	16	CS
VK-MOP-IR	729808-0-0-1	18	CS
VK-MOP-IR	729809-0-0-1	18	CS
VKMX0275	722026-0-0-1	24	CS
VKSE0250	729290-0-0-1	24	CS
VKSE0250	729291-0-0-1	24	CS
VKSE0250	729292-0-0-1	24	CS
VKSE0250	729293-0-0-1	24	CS
VKSE0250	729294-0-0-1	24	CS
VKSE0250	729295-0-0-1	24	CS
VKSE0250	729296-0-0-1	24	CS
VKSE0250	729297-0-0-1	24	CS
VKSE0250	730444-0-0-1	24	CS
VKSE0250	730613-0-0-1	24	CS
VKSE0250	730614-0-0-1	24	CS
VKSE0250	730615-0-0-1	24	CS
VKSE0250	730616-0-0-1	24	CS

Processing Run Start Date/Time: 06-Oct-2019 09:22:03 pm      Approx. Downtime (hours): 0.00  
Processing Run End Date/Time: 07-Oct-2019 06:52:03 am

<b>Minimum Specified Dose (kGy):</b> 30.0	<b>Minimum Delivered Dose (kGy):</b> 33.1
<b>Maximum Specified Dose (kGy):</b> 50.0	<b>Maximum Delivered Dose (kGy):</b> 45.0

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 10/8/2019 at 7:55 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 56260A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VKSE0250	730617-0-0-1	24	CS
VKSE0250	730618-0-0-1	24	CS
VKSE0250	730619-0-0-1	24	CS
VKSE0250	730620-0-0-1	24	CS
VKSE0250	730621-0-0-1	24	CS
VKSE0250	730815-0-0-1	24	CS

Processing Run Start Date/Time: 06-Oct-2019 09:22:03 pm      Approx. Downtime (hours): 0.00  
Processing Run End Date/Time: 07-Oct-2019 06:52:03 am

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**Brandie McCurry (QS/RC Technician)**

Document Content Revision: 1

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