



## 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:	695681-0-0-1
Manufacturing Date:	04/03/2019
Expiration Date:	04/2021

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### Sterility

Gamma Processing Run ID:	54928A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.9 kGy to 46.7 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, April 10, 2019

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# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 54928A


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
EZMP0350	695681-0-0-1	16	CS
HCPM5051	693702-0-0-1	18	CS
LVK-MOP-IR	690484-0-0-1	18	CS
LVK-MOP-IR	690485-0-0-1	18	CS
LVK-MOP-IR	690486-0-0-1	18	CS
LVK-MOP-IR	690487-0-0-1	18	CS
TMVKMOPIR	695157-0-0-1	18	CS
VKMX0375	690768-0-0-1	24	CS
VKMX0375	690769-0-0-1	24	CS
VKMX0375	690771-0-0-1	24	CS
VKMX0375	690772-0-0-1	24	CS
VKMX0375	690773-0-0-1	24	CS
VKMX0375	690774-0-0-1	24	CS
VKMX0375	690775-0-0-1	24	CS
VKSE0250	688110-0-0-1	24	CS

Processing Run Start Date/Time: 06-Apr-2019 05:05:46 am      Approx. Downtime (hours): 0.40  
Processing Run End Date/Time: 06-Apr-2019 01:23:23 pm

<b>Minimum Specified Dose (kGy):</b> 30.0	<b>Minimum Delivered Dose (kGy):</b> 33.9
<b>Maximum Specified Dose (kGy):</b> 50.0	<b>Maximum Delivered Dose (kGy):</b> 46.7

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 4/7/2019 at 8:20 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.