



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:	EZMP0350
Lot Number:	702477-0-0-1
Manufacturing Date:	05/20/2019
Expiration Date:	05/2021

Sterility

Gamma Processing Run ID:	55657A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	31.7 kGy to 43.8 kGy
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
coc@contecinc.com

Friday, July 19, 2019

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DID: 15001B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55657A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
EZMP0350	702477-0-0-1	16	CS
HCKM3054	715815-0-0-1	24	CS
LVK-MOP-IR	692572-0-0-1	18	CS
LVK-MOP-IR	692573-0-0-1	18	CS
LVK-MOP-IR	692574-0-0-1	18	CS
VKSE0250	712861-0-0-1	24	CS
VKSE0250	712862-0-0-1	24	CS
VKSE0250	712863-0-0-1	24	CS
VKSE0250	712864-0-0-1	24	CS
VKSE0250	712865-0-0-1	24	CS
VKSE0250	712866-0-0-1	24	CS
VKSE0250	712867-0-0-1	24	CS

Processing Run Start Date/Time:	14-Jul-2019 11:23:18 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	14-Jul-2019 06:36:53 pm		

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	31.7
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	43.8

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 7/16/2019 at 6:49 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.

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VKSE0250	712862-0-0-1	24	CS
VKSE0250	712863-0-0-1	24	CS
VKSE0250	712864-0-0-1	24	CS
VKSE0250	712865-0-0-1	24	CS
VKSE0250	712866-0-0-1	24	CS
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