



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:	VKMX0375
Lot Number:	1166267-0-0-1
Manufacturing Date:	07/21/2025
Expiration Date:	07/2027

Sterility

Gamma Processing Run ID:	1153-13714A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	32.5 kGy to 44.5 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
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
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Monday, August 11, 2025

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Page 1 of 1

DID: 15461B

STERIS: Gamma Certificate Of Processing

Prepared For CONTEC INC (1963)

Gamma Process Run ID 1153-13714A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VK-MOP-IR	1166315-0-0-1	18	Case
VKSE0250	1164301-0-0-1	24	Case
EZMP0350	1165693-0-0-1	16	Case
VKMX0275	1163185-0-0-1	24	Case
VKMX0375	1166267-0-0-1	24	Case
VKSE0350	1165712-0-0-1	30	Case
VKSE0350	1165713-0-0-1	30	Case
VKSE0350	1165714-0-0-1	30	Case
VKSE0350	1165715-0-0-1	30	Case
VKSE0350	1165716-0-0-1	30	Case
VKSE0350	1165717-0-0-1	30	Case
VKSE0350	1165718-0-0-1	30	Case

Processing Run Start Date 01-Aug-2025 3:15 PM

Processing Run End Date 02-Aug-2025 4:11 AM

Minimum Specified Dose (kGy)	30.0	Minimum Delivered Dose (kGy)	32.5
Maximum Specified Dose (kGy)	50.0	Maximum Delivered Dose (kGy)	44.5

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

Signature Manifest

Reviewed and E-Signed By: **Kimberly Jackson (Quality Analyst)**

DateTime Esigned 04-Aug-2025 8:59 AM

Document Content Revision 1

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 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137-1:2015.

Processing Location

2072 Southport Road
Spartanburg, SC 29306
United States of America
Phone: 864-582-3041