



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:	1168870-0-0-1
Manufacturing Date:	08/05/2025
Expiration Date:	08/2027

Sterility

Gamma Processing Run ID:	1153-13821A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	32.8 kGy to 45.9 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

QC Supervisor
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Tuesday, August 12, 2025

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DID: 15461B

STERIS: Gamma Certificate Of Processing

Prepared For CONTEC INC (1963)

Gamma Process Run ID 1153-13821A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VKSE0250	1169393-0-0-1	24	Case
VKSE0250	1169394-0-0-1	24	Case
VKSE0250	1170090-0-0-1	24	Case
VKSE0250	1170091-0-0-1	24	Case
VKSE0250	1170092-0-0-1	24	Case
VKSE0250	1170093-0-0-1	24	Case
VKSE0250	1170094-0-0-1	24	Case
VKSE0250	1170095-0-0-1	24	Case
VKSE0250	1170096-0-0-1	24	Case
VKSE0250	1170097-0-0-1	24	Case
VKMX0375	1168870-0-0-1	24	Case
VKMX0375	1168871-0-0-1	24	Case
VKMX0375	1168872-0-0-1	24	Case
VKMX0375	1168873-0-0-1	24	Case
VKMX0375	1168874-0-0-1	24	Case
VKMX0375	1168875-0-0-1	24	Case
VKMX0375	1168876-0-0-1	24	Case
VKMX0375	1168877-0-0-1	24	Case
VKMX0375	1168878-0-0-1	24	Case
VKMX0375	1168879-0-0-1	24	Case

Processing Run Start Date 10-Aug-2025 4:37 AM

Processing Run End Date 10-Aug-2025 4:18 PM

Minimum Specified Dose (kGy)	30.0	Minimum Delivered Dose (kGy)	32.8
Maximum Specified Dose (kGy)	50.0	Maximum Delivered Dose (kGy)	45.9

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 10-Aug-2025 5:05 PM

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.

Product Code

Lot Number

Quantity UOM

Processing Location

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