



## 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:	VKSE0150
Lot Number:	1118712-0-0-1
Manufacturing Date:	01/27/2025
Expiration Date:	01/2027

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### Sterility

Gamma Processing Run ID:	1153-12194A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	32.8 kGy to 46.3 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137)

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QC Supervisor  
coc@contecinc.com

Tuesday, February 04, 2025

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DID: 20037A

# STERIS: Gamma Certificate Of Processing

Prepared For CONTEC INC (1963)

Gamma Process Run ID 1153-12194A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BLVKMOPIR	1119811-0-0-1	18	Case
VKSE0250	1117993-0-0-1	24	Case
VKSE0250	1117994-0-0-1	24	Case
VKSE0250	1117995-0-0-1	24	Case
VKSE0250	1117996-0-0-1	24	Case
VKSE0250	1117997-0-0-1	24	Case
VKSE0250	1117998-0-0-1	24	Case
VKSE0250	1118500-0-0-1	24	Case
VKSE0250	1118501-0-0-1	24	Case
VKSE0250	1118502-0-0-1	24	Case
VKSE0250	1118503-0-0-1	24	Case
VKSE0250	1118504-0-0-1	24	Case
VKSE0250	1118505-0-0-1	24	Case
VKSE0250	1118506-0-0-1	24	Case
VKSE0250	1118507-0-0-1	24	Case
VKSE0150	1118711-0-0-1	27	Case
VKSE0150	1118712-0-0-1	27	Case

Processing Run Start Date 30-Jan-2025 11:10 PM

Processing Run End Date 31-Jan-2025 2:23 PM

Minimum Specified Dose (kGy)	30.0	Minimum Delivered Dose (kGy)	32.8
Maximum Specified Dose (kGy)	50.0	Maximum Delivered Dose (kGy)	46.3

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

**Gamma Process Run Approval authorized by STERIS**

DateTime Esigned 31-Jan-2025 3:24 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.

## Processing Location

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

Document ID: 142081

Product Code

Lot Number

Quantity

UOM