



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:	1004460-0-0-1
Manufacturing Date:	07/12/2023
Expiration Date:	07/2025

Sterility

Gamma Processing Run ID:	1153-8303A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	31.3 kGy to 48.1 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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Tuesday, July 25, 2023

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DID: 15461B

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC INC (1963)

Gamma Process Run ID 1153-8303A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BLVKMOPIR	1003612-0-0-1	18	Case
EZMP0350	1004441-0-0-1	16	Case
HCKM3053	1004469-0-0-1	24	Case
HCKM3054	1004482-0-0-1	24	Case
MVK-MOP-IR	999300-0-0-1	18	Case
MVK-MOP-IR	999301-0-0-1	18	Case
VKMX0375	1004459-0-0-1	24	Case
VKMX0375	1004460-0-0-1	24	Case
VKSE0250	991470-0-0-1	24	Case
VKSE0250	993467-0-0-1	24	Case
VKSE0250	993468-0-0-1	24	Case
VKSE0250	993469-0-0-1	24	Case
VKSE0250	993473-0-0-1	24	Case
VKSE0250	993482-0-0-1	24	Case
VKSE0250	993483-0-0-1	24	Case
VKSE0350	1004020-0-0-1	30	Case

Processing Run Start Date: 22-Jul-2023 1:34 PM

Processing Run End Date: 23-Jul-2023 3:04 AM

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	31.3
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	48.1

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

Gamma Process Run Approval authorized by STERIS

Date/Time: 23-Jul-2023 6:01 AM

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: 98061

Product Code

Lot Number

Quantity

UOM