



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:	995720-0-0-1
Manufacturing Date:	06/05/2023
Expiration Date:	06/2025

Sterility

Gamma Processing Run ID:	1153-8008A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	32.8 kGy to 41.8 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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Thursday, June 15, 2023

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DID: 15461B

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC INC (1963)

Gamma Process Run ID 1153-8008A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
HCKM3053	995723-0-0-1	24	Case
VKMX0375	995718-0-0-1	24	Case
VKMX0375	995719-0-0-1	24	Case
VKMX0375	995720-0-0-1	24	Case
VKSE0250	991397-0-0-1	24	Case
VKSE0250	991398-0-0-1	24	Case
VKSE0250	991399-0-0-1	24	Case
VKSE0250	991400-0-0-1	24	Case
VKSE0250	991401-0-0-1	24	Case
VKSE0250	991402-0-0-1	24	Case
VKSE0250	991403-0-0-1	24	Case
VKSE0250	991404-0-0-1	24	Case
VKSE0250	991405-0-0-1	24	Case

Processing Run Start Date: 08-Jun-2023 10:20 PM

Processing Run End Date: 09-Jun-2023 2:56 PM

Minimum Specified Dose (kGy): 30.0

Minimum Delivered Dose (kGy): 32.8

Maximum Specified Dose (kGy): 50.0

Maximum Delivered Dose (kGy): 41.8

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 09-Jun-2023 4:31 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