



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:	VKMX0275
Lot Number:	790029-0-0-1
Manufacturing Date:	07/30/2020
Expiration Date:	07/2022

Sterility

Gamma Processing Run ID:	115052A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	32.0 kGy to 46.0 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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Monday, August 31, 2020

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Page 1 of 1

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CERTIFICATE OF PROCESSING

Prepared for CONTEC INC

Gamma Processing Run ID 58382A (Spartanburg / IR-097) and 115052A (Libertyville I / IR-139)

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BLVKMOPIR	791135-0-0-1	18	CS
VKMX0275	789751-0-0-1	24	CS
VKMX0275	789752-0-0-1	24	CS
VKMX0275	790029-0-0-1	24	CS

Processing Run Start Date/Time: 06 AUG 2020 07:01:24 Approx. Downtime (hours): 0.00
Processing Run End Date/Time: 25 AUG 2020 22:04:32

Minimum Specified Dose (kGy): 30.0	Minimum Delivered Dose (kGy): 32.0*
Maximum Specified Dose (kGy): 50.0	Maximum Delivered Dose (kGy): 46.0*

Other Information: Please reference NC-03403. Product meets Customer specifications. A nonconformity occurred during this irradiation run – Reference Customer disposition.

*Minimum and Maximum Delivered Dose references cumulative dose imparted on product.

Prepared By: [Signature] Title: QS/RC Analyst Date: 8.26.2020
QA Approved: [Signature] Title: QS/RC Manager Date: 8/26/2020

The product run described above was processed in accordance with STERIS Quality System requirements and the approved process parameters. STERIS facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STERIS operates under a quality system which meets the requirements of the FDA QSR and ISO 13485. STERIS adheres to requirements provided through ANSI/AAMI/ISO 11137 and EN 552

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