



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:	795241-0-0-1
Manufacturing Date:	08/19/2020
Expiration Date:	08/2022

Sterility

Gamma Processing Run ID:	58533A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	32.6 kGy to 45.0 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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Wednesday, September 02, 2020

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Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID **58533A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
HCKM3052	793648-0-0-1	24	CS
VKMX0275	795239-0-0-1	24	CS
VKMX0275	795240-0-0-1	24	CS
VKMX0275	795241-0-0-1	24	CS
VKMX0275	795242-0-0-1	24	CS
VKMX0275	795244-0-0-1	24	CS
VKSE0250	798855-0-0-1	24	CS
VKSE0250B	797262-0-0-1	27	CS
VKSE0250B	797263-0-0-1	27	CS
VKSE0250B	797264-0-0-1	27	CS
VKSE0250B	797265-0-0-1	27	CS

Processing Run Start Date/Time: 31-Aug-2020 01:49:28 pm Approx. Downtime (hours): 0.00
Processing Run End Date/Time: 31-Aug-2020 08:35:29 pm

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	32.6
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	45.0

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

Signature Manifest



Reviewed and E-Signed By
Brandie McCurry (QS/RC Technician)
Document Content Revision: 1

Signed On 9/1/2020 at 8:40 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:

STERIS
2072 Southport Road
Spartanburg, SC 29306
Phone: 864-582-3041
Fax: 864-582-4075

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, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.