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:	805998-0-0-1
Manufacturing Date:	10/07/2020
Expiration Date:	10/2022

Sterility

Gamma Processing Run ID:	58742A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	32.2 kGy to 43.3 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10^{-6} (SAL determined by test method AAMI/ISO 11137)

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Certificate Of Processing

Prepared for **CONTEC INC**

STERIS

Gamma Process Run ID **58742A**

Product Code	Product Lot Number	Quantity	UOM
MVK-MOP-IR	808804-0-0-1	18	CS
MVK-MOP-IR	808805-0-0-1	18	CS
VKMX0275	806350-0-0-1	24	CS
VKMX0275	806351-0-0-1	24	CS
VKMX0375	805998-0-0-1	24	CS
VKMX0375	805999-0-0-1	24	CS
VKMX0375	806352-0-0-1	24	CS
VKMX0375	806353-0-0-1	24	CS
VKMX0375	806354-0-0-1	24	CS
VKSE0250	807560-0-0-1	24	CS
VKSE0250	807561-0-0-1	24	CS
VKSE0250	807562-0-0-1	24	CS
VKSE0250	807563-0-0-1	24	CS
VKSE0250	807564-0-0-1	24	CS
VKSE0250	807565-0-0-1	24	CS
VKSE0250	807566-0-0-1	24	CS

Processing Run Start Date/Time:	16-Oct-2020 03:54:01 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	16-Oct-2020 11:37:37 am		

Minimum Specified Dose (kGy):	**30.0**	**Minimum Delivered Dose (kGy):**	**32.2**
Maximum Specified Dose (kGy):	**50.0**	**Maximum Delivered Dose (kGy):**	**43.3**

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 10/19/2020 at 6:48 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.