



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:	690527-0-0-1
Manufacturing Date:	03/19/2019
Expiration Date:	03/2021

Sterility

Gamma Processing Run ID:	54875A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	32.8 kGy to 45.9 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
coc@contecinc.com

Wednesday, April 03, 2019

NORTH AMERICA

Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA
tel: +1 864 503 8333
fax: +864 503 8444

EUROPE

Contec, Inc.
ZI du Prat - R.P. 3707
F-56037 VANNES Cedex France
tel: +33 (0)2 97 43 76 98
fax: +33 (0) 97 43 76 86

ASIA

Contec Cleanroom Technology (Suzhou) Co., Ltd.
17 Longyun Road
Suzhou Industrial Park, Suzhou 215024 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

Page 1 of 1

web: www.contecinc.com
e-mail: info@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 54875A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
HCPM5051	693105-0-0-1	18	CS
LVK-MOP-IR	680254-0-0-1	18	CS
LVK-MOP-IR	680256-0-0-1	18	CS
LVK-MOP-IR	690476-0-0-1	18	CS
LVK-MOP-IR	690477-0-0-1	18	CS
LVK-MOP-IR	692556-0-0-1	18	CS
LVK-MOP-IR	692557-0-0-1	18	CS
VK-MOP-IR	690518-0-0-1	18	CS
VK-MOP-IR	690519-0-0-1	18	CS
VKMX0275	690526-0-0-1	24	CS
VKMX0275	690527-0-0-1	24	CS
VKMX0375	686331-0-0-1	24	CS
VKMX0375	686332-0-0-1	24	CS
VKMX0375	688121-0-0-1	24	CS
VKMX0375	690767-0-0-1	24	CS
VKSE0250B	681330-0-0-1	27	CS
VKSE0250B	681331-0-0-1	27	CS

Processing Run Start Date/Time: 31-Mar-2019 02:12:07 am Approx. Downtime (hours): 0.00
Processing Run End Date/Time: 31-Mar-2019 10:27:28 am

Minimum Specified Dose (kGy): 30.0	Minimum Delivered Dose (kGy): 32.8
Maximum Specified Dose (kGy): 50.0	Maximum Delivered Dose (kGy): 45.9

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 4/1/2019 at 8:30 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.