



## 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:       | LVK-MOPIR    |
| Lot Number:         | 737863-0-0-1 |
| Manufacturing Date: | 11/05/2019   |
| Expiration Date:    | 11/2021      |

---

### Sterility

|                             |                                                                 |
|-----------------------------|-----------------------------------------------------------------|
| Gamma Processing Run ID:    | 56544A                                                          |
| Irradiation Dose Specified: | 30 kGy to 50 kGy                                                |
| Irradiation Dose Delivered: | 31.7 kGy to 45.3 kGy                                            |
| Validated Sterile Product:  | Validation Sterile packets available upon request.              |
| Sterility Assurance Level:  | 10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137) |

---

A handwritten signature in black ink, appearing to read "C. Duffee".

QC Supervisor  
coc@contecinc.com

Wednesday, November 13, 2019

#### NORTH AMERICA

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

web: [www.contecinc.com](http://www.contecinc.com)  
e-mail: [info@contecinc.com](mailto:info@contecinc.com)

Page 1 of 1

DID: 1821B

# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56544A

| <u>Product Code</u> | <u>Product Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|---------------------|---------------------------|-----------------|------------|
| LVK-MOP-IR          | 737863-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 737864-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 737866-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 737867-0-0-1              | 18              | CS         |
| VKSE0250            | 736369-0-0-1              | 24              | CS         |
| VKSE0250            | 736370-0-0-1              | 24              | CS         |
| VKSE0250            | 736371-0-0-1              | 24              | CS         |
| VKSE0250            | 736372-0-0-1              | 24              | CS         |
| VKSE0250            | 736373-0-0-1              | 24              | CS         |
| VKSE0250            | 736374-0-0-1              | 24              | CS         |
| VKSE0250            | 736375-0-0-1              | 24              | CS         |
| VKSE0250            | 736376-0-0-1              | 24              | CS         |
| VKSE0250            | 736377-0-0-1              | 24              | CS         |
| VKSE0250            | 736379-0-0-1              | 24              | CS         |
| VKSE0250            | 736380-0-0-1              | 24              | CS         |
| VKSE0250            | 736381-0-0-1              | 24              | CS         |
| VKSE0250            | 736382-0-0-1              | 24              | CS         |

Processing Run Start Date/Time: 10-Nov-2019 01:29:52 pm

Approx. Downtime (hours): 1.20

Processing Run End Date/Time: 10-Nov-2019 11:58:23 pm

|                                      |             |                                      |             |
|--------------------------------------|-------------|--------------------------------------|-------------|
| <b>Minimum Specified Dose (kGy):</b> | <b>30.0</b> | <b>Minimum Delivered Dose (kGy):</b> | <b>31.7</b> |
| <b>Maximum Specified Dose (kGy):</b> | <b>50.0</b> | <b>Maximum Delivered Dose (kGy):</b> | <b>45.3</b> |

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 11/11/2019 at 2:05 PM

UTC / GMT Offset (hh:mm): -5:00

### 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.

# Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56544A

| <u>Product Code</u> | <u>Product Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|---------------------|---------------------------|-----------------|------------|
| VKSE0250            | 736383-0-0-1              | 24              | CS         |
| VKSE0250            | 736384-0-0-1              | 24              | CS         |
| VKSE0250            | 736385-0-0-1              | 24              | CS         |
| VKSE0250            | 736386-0-0-1              | 24              | CS         |
| VKSE0250            | 736387-0-0-1              | 24              | CS         |

Processing Run Start Date/Time: 10-Nov-2019 01:29:52 pm      Approx. Downtime (hours): 1.20  
Processing Run End Date/Time: 10-Nov-2019 11:58:23 pm

Minimum Specified Dose (kGy): 30.0      Minimum Delivered Dose (kGy): 31.7  
Maximum Specified Dose (kGy): 50.0      Maximum Delivered Dose (kGy): 45.3

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 11/11/2019 at 2:05 PM

UTC / GMT Offset (hh:mm): -5:00

### 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.