



## 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.

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|                     |              |
|---------------------|--------------|
| Product Code:       | LVK-MOPIR    |
| Lot Number:         | 793635-0-0-1 |
| Manufacturing Date: | 08/06/2020   |
| Expiration Date:    | 08/2022      |

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### Sterility

|                             |                                                                 |
|-----------------------------|-----------------------------------------------------------------|
| Gamma Processing Run ID:    | 58424A                                                          |
| Irradiation Dose Specified: | 30 kGy to 50 kGy                                                |
| Irradiation Dose Delivered: | 34.9 kGy to 47.9 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) |

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

QC Supervisor  
coc@contecinc.com

Friday, August 14, 2020

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DID: 1821B

# Certificate Of Processing

Prepared for **CONTEC INC**



Gamma Process Run ID **58424A**

| <u>Product Code</u> | <u>Product Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|---------------------|---------------------------|-----------------|------------|
| LVK-MOP-IR          | 793634-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 793635-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 793636-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 793638-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 795170-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 795171-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 795172-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 795173-0-0-1              | 18              | CS         |
| LVK-MOP-IR          | 795174-0-0-1              | 18              | CS         |

|                                 |                         |                           |      |
|---------------------------------|-------------------------|---------------------------|------|
| Processing Run Start Date/Time: | 13-Aug-2020 02:11:30 am | Approx. Downtime (hours): | 0.00 |
| Processing Run End Date/Time:   | 13-Aug-2020 08:52:54 am |                           |      |

|                                      |             |                                      |             |
|--------------------------------------|-------------|--------------------------------------|-------------|
| <b>Minimum Specified Dose (kGy):</b> | <b>30.0</b> | <b>Minimum Delivered Dose (kGy):</b> | <b>34.9</b> |
| <b>Maximum Specified Dose (kGy):</b> | <b>50.0</b> | <b>Maximum Delivered Dose (kGy):</b> | <b>47.9</b> |

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

## Signature Manifest



Reviewed and E-Signed By  
**Danny Vassey (QS & RC Technician I)**  
Document Content Revision: 1

Signed On 8/13/2020 at 1:48 PM  
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.